UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES *ex rel.*,
DONALD LYNCH, M.D.,
Plaintiff-Relator,

vs.

UNIVERSITY OF CINCINNATI
MEDICAL CENTER, LLC, *et al.*,
Defendants.

Case No. 1:18-cv-587
Dlott, J.
Litkovitz, M.J.

ORDER AND REPORT AND RECOMMENDATION

I. Introduction

Plaintiff-Relator Dr. Donald Lynch, M.D., filed this action on August 20, 2018, claiming violations of the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*. (Doc. 1). Relator named three defendants in the original complaint: University of Cincinnati Medical Center, LLC (UCMC), an Ohio nonprofit corporation; University of Cincinnati Physicians, Inc. (UCP), an Ohio corporation; and UC Health, LLC (UC Health), an Ohio not for profit limited liability company. (*Id.*, ¶ 1). Relator alleges that from December 2015 through the date of the complaint, these three defendants knowingly submitted false claims for payment to the United States related to medical procedures performed by their agents. (*Id.*, ¶ 2). Relator claims that the procedures, Transcatheter Aortic Valve Replacements (TAVRs), were not "reasonable and necessary for the diagnosis or treatment of illness or injury" under 42 U.S.C. § 1395y(a)(1)(A). (*Id.*). Relator seeks to recover damages and civil penalties from defendants on behalf of the United States for their presentment of allegedly false and fraudulent claims for payment to government medical benefit programs.[1] (*Id.*, ¶ 3).

[1] On April 16, 2019, the United States filed a Notice of Election to Decline Intervention. (Doc. 4).

This matter is before the Court on UCMC and UC Health's motion to dismiss and related memoranda (Docs. 10, 16, 18); UCP's first and second motions to dismiss and related memoranda (Docs. 17, 25, 34, 38); UCMC and UC Health's motion to strike the amended complaint, Relator's motion for leave to file an amended complaint, and related memoranda (Docs. 23, 26, 27, 28, 32); and the United States of America's Statement of Interest and related memoranda (Docs. 35, 39, 40).

II. Preliminary motions

1. Request for oral argument

Defendant UCP includes a request for oral argument in the caption of its motion to dismiss Relator's proposed amended complaint. (Doc. 25). Defendant UCP has not "succinctly explained" the grounds for its request in the body of its motion as required by S.D. Ohio Civ. R. 7.1(b)(2). Further, oral argument is not "essential to the fair resolution of the case." *Id.* The Court's review of the facts is limited to the allegations of the complaint and attached exhibits, and the parties have thoroughly briefed the applicable legal issues. UCP's request for oral argument is therefore denied.

2. Motion to strike the amended complaint/motion to amend the complaint

Defendants UCMC and UC Health (the UC Health defendants) filed a motion to dismiss the complaint for failure to state a claim for relief on June 14, 2019. (Doc. 10). After the motion was fully briefed (Docs. 16, 18), and after defendant UCP had filed its motion to dismiss the complaint on July 22, 2019 (Doc. 17), Relator filed an amended complaint without first seeking leave of court. (Doc. 20). The proposed amended complaint, which Relator filed on August 12, 2019, seeks to modify the allegations of the complaint; name a fourth defendant, University of

Cincinnati Physicians Company, LLC/dba UC Physicians (UC Physicians)[2]; and add a claim for conspiracy against all defendants under 31 U.S.C. § 3729(a)(1)(C).

The UC Health defendants move to strike the amended complaint. (Doc. 23). They first argue that Relator did not timely file the amended complaint within 21 days after the UC Health defendants served their motion to dismiss (*see* Doc. 10), and Relator filed the amended complaint without first seeking leave of court as required under Fed. R. Civ. P. 15(a)(2). In addition, they argue that because Relator was precluded from amending his complaint as a matter of course, he was required to seek leave to add UC Physicians as a defendant under Fed. R. Civ. P. 21, which governs amending a complaint to add a new party. (Doc. 23 at 6-8).

Relator filed a memorandum opposing the UC Health defendants' motion to strike the amended complaint on September 16, 2019. (Doc. 26). Relator argues that the amended complaint was timely filed as it relates to his claims against the originally named defendants, and he was not required to seek leave to add UC Physicians as a new defendant under Fed. R. Civ. P. 21. Relator further contends that the motion to strike is moot because he filed a contemporaneous motion for leave to amend the complaint (Doc. 27) with his memorandum in opposition to defendants' motion to strike.

The UC Health defendants filed a combined reply in support of their motion to strike the amended complaint (Doc. 20) and response in opposition to Relator's motion for leave to file his amended complaint (Doc. 27). (Doc. 28). The UC Health defendants oppose the motion for leave to amend under Fed. R. Civ. P. 15(a)(2), asserting that neither the original complaint nor the proposed amended complaint can withstand their motion to dismiss; therefore, amendment would be futile. (Doc. 28 at 2; *see Saint Torrance v. Firstar*, 529 F. Supp. 2d 836, 844-45 (S.D.

[2] The parties refer to University of Cincinnati Physicians Company, LLC/dba UC Physicians as "UC Physicians" or "UCPC."

Ohio 2007)). They argue that the complaint fails to state a claim for relief under the FCA, and the proposed amendment does not cure the defect. They incorporate their arguments from their motion to dismiss the original complaint (Doc. 10) and identify three deficiencies they addressed in the motion which the proposed amended complaint purportedly does not cure. First, the UC Health defendants argue that Relator's claim is premised on their alleged failure to comply with a "nonbinding guidance document," which is not a cognizable theory of liability under the FCA. (Doc. 28). Second, they contend that Relator has not alleged with particularity that they "actually presented any false or fraudulent claims for payment to the government." (*Id.*). Third, defendants argue that Relator has not established that their "alleged noncompliance was material to the government's decision to pay the claim." (*Id.*, citing Doc. 10 at 14). The UC Health defendants urge the Court to review the alleged "legal insufficiencies" of the proposed amended complaint, deny plaintiff's motion for leave to amend based on futility of the amendment, and dismiss the case under Fed. R. Civ. P. 12(b)(6). (*Id.* at 6).

Relator argues in reply that the Court should grant him leave to amend the complaint because the proposed amendment would not be futile. (Doc. 32). Relator argues that his FCA claim is premised on the violation of substantive rules which carry the force of law; the complaint as amended specifically alleges that the UC Health defendants have presented false claims; and the amended complaint adequately pleads materiality.

The Court will deny the UC Health defendants' motion to strike the amended complaint (Doc. 23) as moot and grant plaintiff leave to file the proposed amended complaint (Doc. 27-1). Relator did not unduly delay seeking leave to amend, there is no evidence of bad faith on Relator's part, defendants will not be unduly prejudiced by the amendment, and the amendment would not be futile. *Coe v. Bell,* 161 F.3d 320, 341-42 (6th Cir. 1998) (citing *Brooks v. Celeste*,

39 F.3d 125, 130 (6th Cir. 1994)). The amended complaint adds little of substance to the claims asserted in the original complaint against the UC Health defendants and does not impact resolution of their motion to dismiss the original complaint. Further, defendant UCP has filed a motion to dismiss the amended complaint, and the motion is fully briefed.[3] (Doc. 25). The Court therefore grants Relator's motion for leave to amend the complaint under Fed. R. Civ. P. 15(a). (Doc. 27). The Court will resolve the UC Health defendants' motion to dismiss the original complaint (Doc. 10) and UCP's motion to dismiss the amended complaint (Doc. 25).

3. Motion for leave to file a reply in support of the United States' Statement of Interest (Doc. 40).

The United States filed a Statement of Interest in this case in response to the UC Health defendants' motion to dismiss (Doc. 10). (Doc. 35). The United States asserts that it filed the Statement of Interest to "correct misstatements of law in Defendants' motion and Reply (Docs. 10, 18), which were adopted by reference in Defendant [UCP's] Motion to Dismiss and Joinder (Doc. 25), and futility arguments set forth in [the UC Health defendants'] subsequent briefing. (Doc. 28)." (Doc. 35. at 1, n.1). The United States asserts that it remains "the real party in interest in this action" despite opting to not intervene. (*Id.*, n.2, citing *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933-35 (2009)). The United States submits its statement under the authority of 28 U.S.C. § 517, which gives the United States Attorney General the authority to send "any officer of the Department of Justice [DOJ] . . . to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States. . . ." (Doc. 35 at 1). The United States contends it has "a substantial

[3] Defendant UCP filed its motion to dismiss after Relator filed his proposed amended complaint (Doc. 20) but before he sought leave of court to file the proposed amended complaint (Doc. 27).

interest in the correct interpretation and application of the FCA," which is "the Unites States' principal civil remedy for fraud on the government," in this and similar cases.[4] (*Id.*).

The UC Health defendants filed a response to the Statement of Interest on November 21, 2019, urging the Court to disregard the Statement because neither 28 U.S.C. § 517 nor 31 U.S.C. § 3730 authorize the United States to file the Statement. (Doc. 39). To the extent the Court allows the United States to submit its Statement of Interest, the UC Health defendants have presented arguments responding to the merits of the United States' position. (*Id.*).

The United States moved for leave to file a reply to the UC Health defendants' response on December 13, 2019 and attached a proposed reply. (Docs. 40, 40-1).

The Sixth Circuit Court of Appeals has acknowledged the United States has a right to take "only a limited position" by filing an amicus brief in an FCA case under the authority of 28 U.S.C. § 517, which gives the United States "the ability to 'attend to the interests of the United States' in a pending lawsuit." *U.S. v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 833 n.6 (6th Cir. 2018), *cert. denied sub nom. Brookdale Senior Living Communities, Inc. v. U.S. ex rel. Prather*, 139 S. Ct. 1323 (2019) (*Prather II*). District courts "have interpreted 28 U.S.C. § 517 broadly and typically deny motions to strike" statements of interest filed by officers of the DOJ in pending cases to protect the interests of the United States. *Karnoski v. Trump*, No. 18-51013, 2018 WL 4501484, at *1 (E.D. Mich. Sept. 20, 2018) (citing cases).

The United States is not statutorily barred from filing a Statement of Interest in this case. Section 517 does not contain a time limitation for such a filing, and it does not require the United

[4] The United States seeks to correct what it characterizes as three erroneous arguments made by defendants: (1) individuals can be held liable under 31 U.S.C. § 3729(a)(1) based on an "implied certification" theory "only where conditions of payment are violated and subject to other, undefined strict limits"; (2) only "objectively false" claims, which excludes opinions, are actionable under the FCA; and (3) National Coverage Determinations are simply "agency guidance" and liability under the FCA cannot be based on their violation. (*Id.* at 1-2).

States to obtain the Court's leave to file a statement. *Karnoski,* 2018 WL 4501484, at *2. The United States is therefore granted leave to file its reply in support of its Statement of Interest. (Doc. 40-1). The Court will consider the Statement of Interest, the UC Health defendants' response in opposition, and the United States' reply insofar as the filings are relevant and aid the Court in the resolution of the pending motions to dismiss.

III. Motions to dismiss

1. UC Health defendants' motion to dismiss the original complaint (Doc. 10)

The UC Health defendants filed a motion to dismiss the original complaint on June 14, 2019. (Doc. 10). Relator filed an opposing memorandum on July 19, 2019 (Doc. 16), and the UC Health defendants filed a reply memorandum in support of their motion on August 2, 2019 (Doc. 18). The UC Health defendants move to dismiss the original complaint under Fed. R. Civ. P. 12(b)(b) for failure to state a claim for relief and under Fed. R. Civ. P. 9(b) for failure to plead fraud with particularity.

A. Factual allegations made in the original complaint (Doc. 1)

Relator makes the following factual allegations in the original complaint, which the Court accepts as true for purposes of defendants' motions to dismiss. Relator is a Board Certified Interventional Cardiologist who is licensed to practice medicine in Ohio. (*Id.*, ¶ 10). Relator has been employed as a physician by UCP since the fall of 2015, and he is a member of UCMC's attending medical staff. UCMC is a critical care hospital and not for profit limited liability company organized under the laws of the State of Ohio. (*Id.*, ¶ 12). UC Health is a limited liability company that is organized under the laws of the State of Ohio. (*Id.*). It operates the UC Health System, which includes UCMC and UCP. (*Id.*). UCP is an Ohio corporation which employs physicians and leases them and other employees to University of Cincinnati Physicians

Company, LLC (UC Physicians)[5], of which UC Health is the sole member. (*Id.*, ¶ 13). UCP's alleged mission is to carry out the mission of UCMC and the University of Cincinnati College of Medicine. (*Id.*).

UCMC and UC Health are "institutional providers" who made certifications that they would comply, and did comply, with all Medicare laws and regulations. (Doc. 1, ¶ 43). First, "UCMC or UC Health" submitted Medicare Enrollment Form 855(A), by which defendant certified compliance with Medicare laws such as 42 U.S.C. § 1395y(a)(1)(A).[6] (*Id.*). Second, UCMC and UC Health presented claims for payment using CMS Form 1450 or UB-04, by which "UCMC or UC Health" certified that they complied with 42 C.F.R. § 424.32 and did "not knowingly or recklessly misrepresent or disregard or conceal material facts to the claim submission." (*Id.*). Third, UCMC or UC Health submitted "Annual Hospital Cost Reports," or forms CMS 2252-10, in conjunction with requests for reimbursement for services. (*Id.*). By submitting the reports, "the hospital" certified it was "familiar with the laws and regulations regarding the provision of health care services and that the services identified in the cost report were provided in compliance with such laws and regulations." (*Id.*). In addition, UCP qualifies as a "physician or health care supplier" which was required to submit a CMS 1500 Form to a Medicare contractor for reimbursement of services provided to Medicare patients. (*Id.*, ¶ 45). The CMS 1500 Form certifies that the services "performed by the physicians and identified on the form were medically necessary," and it identifies the treatment or services provided; the entity that provided the services; and the "CPT" codes for services. (*Id.*).

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[5] UC Physicians is not named as a defendant in the original complaint.

[6] Section 1395y(a)(1)(A) provides, in pertinent part, that medical services and procedures will be reimbursed under Medicare only if they are "reasonable and necessary for the diagnosis or treatment of illness or injury. . . ."

TAVR is a technology used in the treatment of aortic stenosis. (*Id.*, ¶ 49). It involves use of a catheter to insert intravascularly a bioprosthetic valve and implant the valve in the orifice of the native aortic valve. (*Id.*). An interventional cardiologist and cardiothoracic surgeon jointly participate in the procedure. (*Id.*). The procedure is performed in a cardiac catherization lab or a hybrid operating room/cardiac catherization lab "with advanced quality imaging" and the capability of accommodating "complicated cases that may require conversion to an open surgical procedure." (*Id.*).

The Centers for Medicare and Medicaid Services (CMS) first issued a National Coverage Determination (NCD) covering TAVR "under Coverage with Evidence Development (CED)." (*Id.*, ¶ 50; Exh. 2 - Medicare National Coverage Determination Manual (MNCD Manual), Chapter 1, Part 1, § 20.32 (Rev. 206, 04-03-18)). The NCD has been reissued several times.[7] (*Id.*). The NCD lists the criteria that hospitals and physician operators must meet before beginning a TAVR program or after a TAVR program is established. (*Id.*). Section 20.32 of the TAVR NCD provides:

> A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a FDA-approved indication and when all of the following conditions are met:
>
> 1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
>
> 2. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.
>
> 3. The patient (preoperatively and postoperatively) is under the care of a heart team; a cohesive, multi-disciplinary, team of medical professionals. The heart

[7] Relator alleges that "the volume criteria" have not been modified. This is an apparent reference to provisions of the NCD that specify the numbers of procedures that a facility or physician must perform to be qualified to begin a TAVR program.

team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

A TAVR can only be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site heart valve surgery program,
b. Cardiac catherization or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
f. Appropriate volume requirements per the applicable qualifications [set forth in the NCD].

(*Id.*, ¶ 51; Exh. 2).

The NCD lists two different sets of "volume requirements" for health care entities. (*Id.*, ¶ 53). The first set applies to a hospital program without TAVR experience. (*Id.*, ¶ 53). UCMC and UC Health fall into this category. (*Id.*, ¶¶ 53, 54). UCMC and UC Health must therefore meet the following volume requirements to be eligible to bill for a TAVR procedure:

a. $\geq$ 50 total AVRs (Aortic Valve Replacements) in the previous year prior to TAVR, including $\geq$ 10 high-risk patients, and;
b. $\geq$ 2 physicians with cardiac surgery privileges, and;
c. $\geq$ 1000 catheterizations per year, including $\geq$ 400 percutaneous coronary intervention s (PCIs) per year.

(*Id.*, ¶ 54; Exh. 2).

Additionally, qualifications to begin a TAVR program for heart teams without AVR experience include:

a. Cardiovascular surgeon with:

i. $\geq$ 100 career AVRs including 10 high-risk patients; or,

ii. ≥ 25 AVRs in one year; or
iii. ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and

b. Interventional cardiologist with:

i. Professional experience with 100 structural heart disease procedures lifetime; or
ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures.

(*Id.*, ¶ 55, Exh. 2).

Dr. Satya S. Shreenivas, M.D., joined UCMC, UCP, and UC Health in 2014 as director of the new Structural Heart Program for the UCMC Heart, Lung & Vascular Institute. (*Id.*, ¶ 56, Exh. 3 - UCMC's "Cardiovascular Insights" publication.). UCMC had constructed a new operating room to perform TAVR procedures. (*Id.*). Relator alleges that beginning in the spring of 2015, "Dr. Shreenivas was concerned with the issue of whether UCMC and UC Health qualified under the applicable NCD for Medicare/Medicaid reimbursement for the TAVR procedures which were anticipated to be performed at UCMC within the Heart, Lung & Vascular Institute." (*Id.*, ¶ 57). Relator refers to an email string between Dr. Shreenivas and other individuals to support this allegation. (*Id.*, Exh. 4). The first email in the string is a March 24, 2015 email that Dr Shreenivas sent to the Chief Medical Officer for "CGS Administrators," Dr. Neil S. Sandler, M.D.[8] In his email, Dr. Shreenivas thanked Dr. Sandler for speaking with him and wrote:

Our question is:

How do you define a program with experience? If we can be considered a program with experience we only have to meet the 20 surgical AVR requirement (which we do). For example, if we did 1-5 TAVR cases for patients that had private insurance or if we did 1-5 cases without requesting reimbursement from Medicare, would that

[8] Relator does not identify CGS or indicate why Dr. Shreenivas sought advice from Dr. Sandler, who Relator indicates was with CMS. (*Id.*, Exh. 4).

be enough to qualify as a program with experience and could we then qualify as an experienced program?

When the NCD was first released, the only way a program could get experience was if they had been part of a clinical trial since the device was not FDA approved. Since then, it is a FDA approved device and private insurance companies are paying for the procedure. Now, a program could get experience and not be part of a trial. I don't think anyone has done this because 1) most patients in this age range > 65 years old are covered by Medicare and 2) not many programs are willing to do cases for free to gain experience.

Any help you could provide would be of immense help.

(*Id.*).

The email string includes Dr. Sandler's April 6, 2015 response that he had "been looking at several avenues to try and answer your question regarding the definition of TAVR experience." (*Id.*). He wrote that he was attaching the decision memo for TAVR, which "may provide some guidance," and he directed Dr. Shreenivas' attention to two particular sections: page 31, table 1 of the pdf. copy, and a subsection for institutional requirements in the section for public comments (Section 7) on page 43 of the pdf. copy. Dr. Sandler opined that those two areas may have some informational value, and he suggested they schedule a brief call to see if they came to the same conclusion once Dr. Shreenivas had an opportunity to review the information. (*Id.*).

Dr. Shreenivas forwarded the email from Dr. Sandler to Dr. Richard Becker, the Chief of the Division of Cardiovascular Health & Disease for the Heart, Lung & Vascular Institute and Director of the Heart, Lung and Vascular Institute, on April 16, 2015. (*Id.*, ¶ 58; Exh. 4). Dr. Shreenivas told Dr. Becker that the "attached CMS decision memo is exhaustive," but the "main points of focus are the table on page 31 and the public comments and CMS responses on pages 43 and 44." (*Id.*, Exh. 4). He told Dr. Becker that he would schedule another call with Dr. Sandler to further discuss the document, and he suggested that they might want to meet to

discuss the matter and "then consider getting this reviewed by our legal financial department." (*Id.*). Dr. Becker responded that they should plan to talk in the coming week and that Lawrence Stalica, who was copied on the email, should join them. (*Id.*). Relator alleges that by forwarding the email string to Dr. Becker and "pursuant to a subsequent conversation," Dr. Shreenivas informed Dr. Becker that UCMC and UC Health did not qualify under the TAVR NCD to bill "a government health benefit program for TAVR procedures because UCMC had not performed at least 50 AVRs within the prior year," and Dr. Shreenivas asked that UCMC's legal department review UCMC's failure "to achieve the minimum number of AVRs. . . ." (*Id.*, ¶ 58).

By November 1, 2015, a "rolling total" of 26 AVRs had been performed at UCMC during the prior year. (*Id.*, ¶ 59, Exh. 5). The total is reflected in an email dated November 1, 2015, that Dr. Shreenivas sent to two cardiac surgeons at UCMC, Dr. Louis and Dr. Alan Simeone, regarding "Aortic valve replacements/timing of tavr program." (*Id.*). Dr. Shreenivas wrote: "We would like to start doing TAVRs soon. A large part of that is making sure we have the surgical aortic valve replacement volume to be able to start the program." (*Id.*). Dr. Shreenivas listed the data he had for the preceding two years up to the date of his email and then asked for a "rough idea of number of cases you might have for AVR in the next 1-2 months," noting he had sent over two patients in the last two weeks and was not sure if there were others. (*Id.*). Relator alleges that no additional information was received in response to Exhibit 5. (*Id.*, ¶ 59).

On November 16, 2015, UCMC, through its HLVI Operations and Implementation Committee, issued a status report on the Structural Heart Program for TAVRs. (*Id.*, ¶ 60, Exh. 6). The report confirmed that the rolling total number of AVRs for the previous year was 26, and it stated: that UCMC would perform "the first TAVR at UC" in one month. (*Id.*, Exh. 6, p.

3). The first anticipated patient was a VA patient and the next three were Medicare patients. (*Id.*, p. 5). Relator alleges that before any billings were submitted to a government-sponsored benefit program for TAVR procedures performed at UCMC, "Dr. Shreenivas again informed UCMC, UCP, and UC Health that billing for these procedures was unlawful." (*Id.*, ¶ 61). Relator bases this allegation on email communications concerning billing for a TAVR procedure performed on December 14, 2015. (*Id.*, ¶¶ 61-66). The first email is attached to the complaint as Exhibit 7. The email is dated January 25, 2016 and was sent from Jamie Hamm, "Coding Mgr., Corporate Coding Services," to an individual name "Tal."[9] Hamm wrote: "The following are IP [inpatient] accounts holding for an OP [operating procedure] note and I believe all of these surgeons fall under you," and she stated that she appreciated Tal's help. (*Id.*, p. 3). The email lists five surgical procedures performed by six different surgeons on dates in December 2015 and 2016, including non-cardiac procedures. (*Id.*). The fifth procedure listed is a TAVR performed by Dr. Shreenivas on December 14, 2015 (No. 04020680).

The Medical Director of UCMC, Dr. William Naber, responded to Hamm's email the same day she sent it. (*Id.*, p. 2). The subject line of his email was: "Re: Inpatient accounts being held for operative report." (*Id.*). The body of the email is cut off on the copy attached to the complaint. (*Id.*). On February 1, 2016, Hamm sent an email to Dr. Naber with the same subject line and informed him that as of that date, she was still missing information from Dr. Shreenivas for the December 14, 2015 TAVR procedure. (*Id.*). Due to Dr. Shreenivas' inaction, Dr. Naber asked Peter Clayton, Executive Director of Business Affairs at the UC Department of Internal Medicine/UC Physicians, if he could "help with the dictation" on Dr. Shreenivas' OP note. (*Id.*; Exh. 7, p. 2). Mr. Clayton wrote to Dr. Shreenivas, "Please

[9] Relator alleges that Hamm was "the billing coordinator for UC Health, UCMC, and UCP." (*Id.*, ¶ 61). Relator also alleges that Hamm wrote the email to Dr. Shreenivas and does not identify "Tal."

complete your dictation on [patient] or advise on difficulties," which Relator alleges was an order from Clayton to Dr. Shreenivas to "complete the dictation so that the patient account could be billed to Medicare." (*Id.*, Exh. 7, pp. 1-2). Dr. Shreenivas advised Mr. Clayton and Dr. Naber in response, "This cannot be billed. Please call me to discuss." (*Id.*, Exh. 7, p. 1). Relator alleges that Dr. Shreenivas delayed completing the OP note and advised that the TAVR could not be billed "because he believed billing Medicare for the December 14, 2015 TAVR procedure was illegal" given UCMC's failure to meet "the threshold requirement of 50 AVRS for the prior year under the Medicare NCD." (*Id.*, ¶¶ 62, 63). On February 3, 2016, Dr. Naber wrote an email to Dr. Shreenivas and Clayton which reads: "I have talked to Craig Cain about this case, he was peripherally aware. We will be billing only Medicare (not the patient) so we still need the dictation to do this properly. Thanks for all of your help clarifying this delicate situation." (*Id.*, Exh. 7, p. 1).

On August 25, Dr. Shreenivas wrote to Rhonda Schlesinger, a billing code manager for UCMC, UCP, and UC Health, and inquired about the billing status for the patients on whom he had performed TAVR. (*Id.*, ¶ 65). Schlesinger provided a TAVR case log in response that identified the TAVR billings "for all TAVR patients," including the billings that had been presented to government programs. (*Id.*, ¶ 66). Relator alleges that he "is aware" that on an unspecified date, Dr. Tim Smith, a former member of UCMC's medical staff and a former UCP employee, told "UCMC and UCPC officials" that "billing government sponsored health care programs for TAVR procedures when the NCD prerequisites had not been met for AVR volume was unlawful." (*Id.*, ¶ 67). Relator alleges that "[t]his information was conveyed to Dr. Gregory Rouan, the Chairman of the Department of Internal Medicine for the University of

Cincinnati, Peter Clayton, Dr. Richard Becker, and Dr. Charles Hattemer, the Associate Chief of Clinical Affairs at UCMC and a member of UCP." (*Id.*).

Relator alleges that Dr. Shreenivas and Dr. Smith both ceased their employment with UCP because they "were concerned, in part, about [the UC defendants'] unlawful conduct." (*Id.*, ¶ 68). He alleges they "began work with The Christ Hospital in 2017." (*Id.*).

UCP physicians Dr. Shreenivas and Dr. Imran Arif performed 33 TAVR procedures at UCMC from December 14, 2015 through August 22, 2017, at least 12 of which were billed to Medicare, CareSource, and the Veterans Administration-TriCare/Champus. (*Id.*, ¶ 69). There were 21 additional procedures performed and billed to government-funded programs between August of 2017 and August 20, 2018.[10] (*Id.*, ¶ 70).

Relator alleges that UCMC, UCP, and UC Health have "breached the bargain" between the United States and themselves by "submitting claims for services that are not defined as reasonable and necessary by the applicable statutory authority." (*Id.*, ¶ 80). Relator alleges, "If the United States had known that the Defendants' submissions for TAVR reimbursement were not reasonable or necessary, the United States would not have paid these claims." (*Id.*, ¶ 81).

Relator alleges as an example of a false claim a reimbursement request for a TAVR procedure performed on December 15, 2015 on Patient RT. (*Id.*, ¶ 82). Relator alleges the claim "was presented by the Defendants on March 17, 2016 pursuant to invoice number 40149750 and paid by the United States." (*Id.*). Relator alleges the CPT Codes for the bill (33361 and 33362) designate TAVR procedures. (*Id.*). According to the complaint, the claim was for a patient whose insurance carrier was the "VA" (Veterans Administration). (*Id.*, ¶ 69).

[10] The chart Relator has submitted shows that the first TAVR (04020680) was performed on December 15, 2015, not December 14, 2015, and that the insurance carrier is the VA (Veterans Administration).

Relator brings three claims for relief based on these allegations. First, Relator alleges that the UC defendants violated 31 U.S.C. § 3729(a)(1)(A) from December 14, 2015 to the present by knowingly presenting, or causing to be presented, false or fraudulent TAVR claims for payment to federally funded health insurance programs. Relator claims that the UC defendants falsely certified that they had complied with federal laws, and the false representations were material to the United States's decision to pay the claims. (*Id.*, ¶¶ 83-86). Relator alleges that defendants UCMC, UC Health, and UCP have submitted, and continue to submit, "false claims relating to Part A (Facility Fees) and Part B (Physician Fees) for treatment provided to Medicare, Medicaid, and Champus patients who are undergoing TAVR procedures." (*Id.*, ¶ 48).

Second, Relator alleges that the UC defendants violated 31 U.S.C. § 3729(a)(1)(B) from December 14, 2015 to the present by knowingly making or using false records, or statements material to a false claim, to have a false TAVR claim paid or approved by the United States in violation of 31 U.S.C. § 3729(a)(1)(B). Relator alleges the representations were material to the United States's decision to pay the TAVR claims; the United States was unaware the records or statements were false; and the United States paid for procedures performed on individuals who were insured by federally-funded health insurance programs in reliance on the accuracy of these claims and/or statements. (*Id.*, ¶¶ 87-92).

Third, Relator alleges that UCMC and UC Health violated 31 U.S.C. § 3729(a)(1)(G) based on their obligation to submit cost reports under CMS-2552, which reconciled payments made to these defendants throughout the calendar year, and to repay the amount of any overpayment to the United States. Relator alleges that defendants UCMC and UC Health have been overpaid by the United States due to their "illegal conduct" in "an amount equal to the sums

presented for all Part A and TAVR services from December 14, 2015 to the present[,] including the cost of the hospital stay." Relator claims that UCMC and UC Health have failed to report overpayments and to return overpayments within 60 days of the date UCMC and UC Health were due to submit yearly CMS-2552 reports to their fiscal intermediaries. (*Id.*, ¶¶ 92-99).

B. Allegations of the Amended Complaint (Doc. 27)

Relator's proposed amended complaint adds little in the way of substance to the allegations made in the original complaint against the UC Health defendants and UCP. Relator suggests in the amended complaint that the party he seeks to add the lawsuit - University of Cincinnati Physicians Company, LLC (UC Physicians), an Ohio not for profit limited liability company - submitted the false claims at issue.[11] (*Id.*, ¶ 14). Relator also alleges that UCMC, UCP, UC Health, and UC Physicians each "presented or caused to be presented claims for reimbursement relating to NCDs and TAVR procedures that did not meet [the] NCD[']s criteria for payment." (*Id.*, ¶ 54). Relator alleges that the parties are interrelated in that UC Health owns and operates UCMC, UCP and UC Physicians.[12] (*Id.*, ¶ 109). Relator also alleges that Dr. Shreenivas joined each of the four entities - UCMC, UCP, UC Health, and UC Physicians - in 2014. (*Id.*, ¶ 64). Relator seeks to add a claim for conspiracy against the original defendants and UC Physicians, alleging that "[a]t least one or more of the conspirators[,] including UC Physicians[,] performed the act in submitting the false claim in furtherance of a conspiracy in order to get the claims identified in [the complaint] paid." (*Id.*, ¶¶ 109, 110). Relator's allegations are based in part on his knowledge of the terms of his own contract, "which indicates

[11] Relator alleges that "[a]ccording to Defendants UC Health and UCMC, UC Physicians submitted the false claims at issue in this case to the United States." (*Id.*, citing Doc. 18, UCMC and UC Health's reply in support of their motion to dismiss the original complaint, p. 8, n.6).

[12] Relators also alleges that UC Health is the "sole member" of UC Physicians. (*Id.*, ¶ 13).

that billing for his professional fees will be made by UCP or UC Health," and in part on what he characterizes as "admissions" by UCMC and UC Health that UC Physicians submitted claims relating to the TAVR procedures at issue.[13] (*Id.*, ¶ 94).

C. Rule 12(b)(6) and Rule 9(b) Standard of Review

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim that consists of mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" will not withstand a motion to dismiss. *Twombly*, 550 U.S. at 555. The Court may grant a Rule 12(b)(6) motion to dismiss if the complaint fails to allege facts "sufficient 'to raise a right to relief above the speculative level,' and to 'state a claim to relief that is plausible on its face.'" *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (quoting *Twombly*, 550 U.S. at 555, 570). A claim is plausible on its face if the allegations allow "the court to draw [a] reasonable inference that the defendant is liable for the alleged misconduct." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). The Court views the complaint in the light most favorable to the plaintiff, presumes the truth of all well-pleaded factual assertions, and draws every reasonable inference in favor of the non-moving party. *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008).

[13] This is an apparent reference to the UC Health defendants' representation in their reply memorandum that upon information and belief, the evidence would show that UC Physicians submitted the claims identified in the complaint. (*See* Doc. 18).

"[D]efendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011). Complaints alleging FCA violations must therefore satisfy Fed. R. Civ. P. 9(b)'s pleading requirement that fraud be pled with particularity. *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017), *reh'g en banc denied*, (6th Cir. Jan. 3, 2018), *cert. denied*, 138 S. Ct. 2582 (2018). "To satisfy Rule 9(b), a complaint of fraud, 'at a minimum, must allege the time, place, and content of the alleged misrepresentation on which [the plaintiff] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.'" *United States ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 444 (6th Cir. 2008) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc. (Bledsoe I)*, 342 F.3d 634, 643 (6th Cir. 2003)). If a relator "pleads a complex and far-reaching fraudulent scheme," the complaint must include "examples of specific false claims" and "identify with specificity 'characteristic examples that are illustrative of the class of all claims covered by the fraudulent scheme'" to survive a motion to dismiss. *Chesbrough*, 655 F.3d at 467 (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys. (Bledsoe II)*, 501 F.3d 493, 510-11 (6th Cir. 2007)).

D. The False Claims Act

Relator alleges that defendants violated the FCA by submitting false claims to federally-funded health insurance programs. The FCA, 31 U.S.C. § 3729 *et seq.*, imposes civil liability on an individual or entity that defrauds the federal government. *Prather II*, 892 F.3d at 826 (citing *Universal Health Services, Inc. v. U.S. ex. rel. Escobar*, _ U.S. _, 136 S. Ct. 1989, 1996 (2016)). The Act imposes liability (1) under 31 U.S.C. § 3729(a)(1)(A) on one who "'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval' to the Federal

Government," *Escobar*, 136 S. Ct. at 1996; (2) under 31 U.S.C. § 3729(a)(1)(B) on one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"; and (3) under 31 U.S.C. § 3729(a)(1)(G) on one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

A "claim" under the FCA "includes direct requests to the government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *See Escobar*, 136 S. Ct. at 1996 (citing § 3729(b)(2)(A)). To state a claim for relief under the FCA, the plaintiff must sufficiently allege four elements: (1) "the defendant made a false statement or created a false record"; (2) with "scienter"; (3) the false statement or record was "material to the Government's decision to make the payment sought in the defendant's claim"; and (4) the defendant presented the false statement or record to the Government, "causing it to pay the claim." *Prather II,* 892 F.3d at 830.

The term "knowingly" as defined under the FCA means that a person, with respect to information (i) has "actual knowledge of the information"; (ii) "acts in deliberate ignorance of the truth or falsity of the information"; or (iii) "acts in reckless disregard to the truth or falsity of the information." *Escobar*, 136 S. Ct. at 1996 (quoting 31 U.S.C. § 3729(b)(1)(A)). "[R]eckless disregard" is sufficient to satisfy the scienter requirement for an FCA violation. *United States ex rel. Wall v. Circle C Constr., L.L.C.*, 697 F.3d 345, 356 (6th Cir. 2012) (quoting *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008)). This level of scienter "target[s] that defendant who has 'buried his head in the sand' and failed to make some inquiry

into the claim's validity." *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (quoting S. Rep. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5286). The defendant's inquiry must be "reasonable and prudent under the circumstances." *Id.* (quoting S. Rep. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5286). "[P]roof of specific intent to defraud" is not required to establish scienter. *Escobar*, 136 S. Ct. at 1999, n.2 (citing 31 U.S.C. § 3729(b)(1)(B)). A plaintiff need only allege scienter generally to satisfy this element at the pleading stage. Fed. R. Civ. P. 9(b).

"Material" under the FCA means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Escobar*, 136 S. Ct. at 1996 (quoting 31 U.S.C. § 3729(b)(4)). The false statement or record is material if a reasonable person would consider it important to "determining his choice of action in the transaction," or if the defendant knew or had reason to know that the person to whom it made the representation would attach this importance to it, even if a reasonable person would not. *Escobar*, 136 S. Ct. at 2002-03 (quoting Restatement (Second) of Torts § 538 (Am. Law Inst. 1977)). The FCA's materiality "standard is demanding." *Id.* at 2003. The FCA "is not 'an all-purpose antifraud statute,'" *Id.* (quoting *Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662, 671 (2008)), or "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* The Court in *Escobar* clarified the materiality standard under the FCA as follows:

> [M]ateriality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation. In tort law, for instance, a matter is material in only two circumstances: (1) [if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, even though a reasonable person would not. . . .

Id. at 2002-03 (internal citations and quotations omitted). The Supreme Court in *Escobar* rejected the proposition that "any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Id.* at 2004.

To establish the "presentment element" of a claim for relief under the FCA, the relator must sufficiently allege that a "false or fraudulent claim was 'presented' to the government." *Ibanez*, 874 F.3d at 914 (quoting *Marlar*, 525 F.3d at 445). "At the pleading stage, this standard is stringent." *Ibanez*, 874 F.3d at 914 (citing *Chesbrough*, 655 F.3d at 470). Where the relator alleges a "complex and far-reaching fraudulent scheme" that violates § 3729(a)(1), he must allege the fraudulent scheme and "identify a representative false claim that was actually submitted to the government." *Id.* (quoting *Chesbrough*, 655 F.3d at 470). "Alternatively, a claim may survive a Rule 12(b)(6) motion if it includes allegations showing 'specific personal knowledge' supporting a 'strong inference that a [false] claim was submitted.'" *Id.* (quoting *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 769 (6th Cir. 2016) (*Prather I*).

E. The Medicare Act

Relator here alleges that the UC Health defendants presented false claims to the Government in violation of the FCA by seeking reimbursement for medical procedures from federally-subsidized health insurance programs, including Medicare, in violation of federal statutes and regulations. Title XVIII of the Social Security Act, more commonly known as the Medicare Act, is a federally subsidized health insurance program governed by the Secretary of Health and Human Services (Secretary). 42 U.S.C. § 1395 et seq. Medicare covers the costs of certain health care services for participants who meet its age, disability, or end-stage renal

disease eligibility requirements. 42 U.S.C. § 1395c-1935i-4. The Secretary is responsible for determining what claims are covered by Medicare. 42 U.S.C. § 1395ff(a).

Part A of the Medicare program deals with hospital insurance. 42 U.S.C. §§ 1395c - 1395i-4. Medicare Part B covers outpatient health care expenses and physician fees. 42 U.S.C. §§ 1395j - 1395w-4. Parts A and B include coverage for various items and services, but they exclude payment for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury. . . ." 42 U.S.C. § 1395y(a)(1)(A).

Medicare is administered for the Department of Health and Human Services by the Center for Medicare and Medicaid Services (CMS). CMS contracts with private insurance companies and "local peer review organizations" (Medicare Administrative Contractors), which together process claims for Medicare beneficiaries. *See* 42 U.S.C. § 1395kk-1(a)(4). Providers agree to abide by all Medicare laws, regulations, and program instructions as part of their standard Medicare Provider Agreement with CMS; providers acknowledge that Medicare's payment of claims is conditioned on the provider's compliance with those terms (*see* Form CMS-855B); and providers must submit signed claim forms to obtain payment for services covered by Medicare. 42 C.F.R. §§ 424.30, 424.33.

Providers of Medicare services must meet and maintain certain enrollment requirements to bill the Medicare Program for services provided to Medicare beneficiaries. 42 C.F.R. § 424.500. Providers must complete and submit a signed enrollment application, often termed the Provider Agreement, by which the signatory attests to the information contained in the application and attests that he is aware of all applicable terms and governing regulations, statutes, and program instructions. 42 C.F.R. § 424.510(d)(3). To enroll and maintain active enrollment

in the Medicare program, providers must comply with applicable Medicare regulations. 42 C.F.R. § 424.516(a)(1).

The Medicare Act does not contain a comprehensive list of items or services covered or excluded by Medicare. *Woodfill v. Sec. of Health and Human Services*, No. 3:11-cv-2236, 2013 WL 2153247, at *1-2 (N.D. Ohio May 15, 2013), *aff'd,* 557 F. App'x 473 (6th Cir. 2014) (citing 68 Fed. Reg. 55634 at 55635). The Act instead "lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program." *Id.* at *2 (citing 68 Fed. Reg. 55634 at 55635). A Medicare payment "is contingent upon a determination 'that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is reasonable and necessary.'" *Id.* (citing 68 Fed. Reg. 55634 at 55635; 42 U.S.C. § 1395y(a)(1)(A)). "The decision as to whether a particular medical item or service is reasonable and necessary is a discretionary decision, reserved to the Secretary." *Id.* (citing *Heckler v. Ringer,* 466 U.S. 602, 617 (1984); 42 U.S.C. § 1395ff(a)(1)). The Secretary decides "whether a particular medical service is reasonable and necessary" by promulgating a generally applicable rule or engaging in individual adjudication. *Id.* (citing *Ringer*, 466 U.S. at 617; 42 U.S.C. § 1395ff(a)(1)). Medicare establishes generally applicable rules for covered items or services through NCDs, which are determinations of national application by the Secretary "granting, limiting, or excluding Medicare coverage for a specific medical [item] or service." *Id.* (quoting 68 Fed. Reg. 55634 at 55635). NCDs are binding on Medicare Administrative Contractors (MACs), who act as agents for the government in reviewing and paying claims submitted by health care providers (*see* 42 U.S.C. § 1395h, 42 C.F.R. §§ 421.3, 421.100), and administrative law judges in Medicare coverage appeals. *Anesthesia Services Associates, PLLC*, No. 3:16-cv-

0549, 2019 WL 7372510, at *2 (M.D. Tenn. Dec. 31, 2019) (citing 42 U.S.C. § 1395ff, 42 C.F.R § 405.1060(a)). *See also Woodfill*, 2013 WL 2153247, at *2 ("An NCD is binding during administrative adjudication" pursuant to 42 C.F.R. § 405.1060(a)(4)). In the absence of an NCD, MACs may issue a "local coverage determination" (LCD), which announces "whether or not a particular item or service is covered" for the specified jurisdiction within which a MAC processes and pays claims on behalf of the CMS. *Anesthesia Services Associates, PLLC*, 2019 WL 7372510, at *2 (citing 42 U.S.C. §§ 1395ff(f)(2), 1395m-1(g)). "In adjudicating coverage appeals, administrative law judges 'give substantial deference' to local coverage determinations, but they are not bound by them." *Id.* (quoting 42 C.F.R. § 405.1062).

F. The parties' arguments

Defendants UCMC and UC Health move to dismiss the original complaint. (Doc. 10). They argue that Relator's claims for relief brought against them under the FCA fail on three grounds. First, they argue that the TAVR NCD is not a "duly promulgated" regulation or a statute. (Doc. 10 at 3). They allege it is a "guidance document" published by the CMS "to aide (sic) in the determination of 'medical necessity.'" They characterize their alleged noncompliance with the TAVR NCD as a "technical violation" which does not constitute "fraud" under the FCA. As support for their position, they aver that the United States Department of Justice (DOJ) has "instructed its attorneys not to bring or participate in FCA cases - like this one - that turn on mere technical violations of agency guidance that has not been passed as a law or published as a regulation." (*Id.*).

Second, the UC Health defendants contend that Relator has not pled his claims of fraud with particularity as required under Fed. R. Civ. P. 9(b). (*Id.*). This ground for dismissal is closely tied to the first. The UC Health defendants argue that the original complaint lacks

particularity because the "whole case turns on alleged violations of a non-binding agency guideline" and "program guidance." (*Id.* at 3-4). They contend that Relator has not alleged additional facts that purportedly are required to establish fraud under the FCA, i.e., that there was an "objective falsehood"; that "the cardiologists who performed the TAVRs were unqualified"; or that "the [TAVR] patients were not good candidates for TAVR." (*Id.*).

Third, the UC Health defendants contend that the complaint must be dismissed because the materiality element is not satisfied. The UC Health defendants argue that Relator has not alleged facts to show that if CMS had known of defendants' alleged non-compliance with the TAVR NCD, the government would not have reimbursed defendants for the TAVR procedures. (*Id.*).

Relator argues in response that the UC Health defendants submitted or caused to be submitted claims for reimbursement for TAVR procedures performed at UCMC that were not medically "reasonable and necessary" under § 1395y(a)(1)(A) and were therefore false. (Doc. 16; *see Escobar*, 136 S. Ct. 1989). Relator alleges that defendants submitted, or caused to be submitted, reimbursement claims that made representations regarding compliance with various federal insurance regulations, but which failed to disclose violations of binding requirements pertaining to the number of procedures that had been performed at UCMC prior to implementing its TAVR program. Relator alleges that the UC defendants sought and obtained reimbursement from the United States for fees incurred in performing TAVR procedures, even though the hospital and its staff had not performed the required number of AVR procedures which were a prerequisite to qualifying as an "experienced" facility authorized to bill the Government for TAVR procedures. Relator alleges that the Government, unaware of defendants' failure to comply with the TAVR program and reimbursement requirements, paid the reimbursement

claims. Relator alleges that the Government would not have paid the claims for reimbursement had it known that the TAVR procedures billed were performed in a facility, and by providers, that did not meet the requirements of the TAVR NCD.

In reply, the UC Health defendants argue that Relator has not stated a claim for relief under the FCA because he does not allege that defendants made an "outright lie or false statement to the Government"; that they billed for services that were not performed; or that the procedures they billed for were not medically necessary or reasonable. (Doc. 18). The UC Health defendants contend that the TAVR NCD is not a law or regulation on which Relator can premise a claim under the FCA, and they allege that they never certified they were in compliance with the NCD. (*Id.* at 3). The UC Health defendants also argue that Relator "re-casts" the "implied certification" theory of liability pled in his complaint as a "false certification" theory in his opposing memorandum by claiming that the UC Health defendants failed to comply with the TAVR NCD despite certifying compliance with it in documents they submitted to the government. (*See* Doc. 16 at 11). The UC Health defendants allege that Relator's "false certification" theory fails because the forms defendants submitted, which allegedly certified compliance with the TAVR NCD, do not relate to or mention NCDs, much less the TAVR NCD, and the claims they submitted do not certify compliance with the TAVR NCD on their face.

G. The UC Health defendants' motion to dismiss should be denied.

i. Theory of liability

The UC Health defendants raise a threshold issue as to whether Relator has abandoned the theory of FCA liability raised in the original complaint by presenting a different theory of FCA liability in the response to the motion to dismiss, which Relator is now bound to pursue. They argue that Relator articulated an "implied certification" theory of liability in the complaint

which he has recast as an "express certification" theory of liability in his memorandum in opposition to their motion to dismiss.

Both implied and express certification theories of liability are cognizable under the FCA. The "implied false certification" theory can apply where a defendant "submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Escobar*, 136 S. Ct. at 1995. The defendant can be held liable if those omissions "render the defendant's representations misleading with respect to the goods or services provided." *Id.* at 1999. An "express false certification" theory can apply "when the defendant is alleged to have signed or otherwise certified to compliance with some law or regulation on the face of the claim submitted." *U.S. ex rel. Hobbs v. MedQuest Associates, Inc.*, 711 F.3d 707, 714 (6th Cir. 2013).

The theory of FCA liability articulated in the complaint is an implied certification theory. Relator's theory is that the claims for payment do more than "merely request payment"; they also "make[] specific representations" about the services provided; and further, defendants' failure to disclose their alleged noncompliance with "material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *See Escobar,* 136 S. Ct. at 2000-01. Relator alleges that the UC Health defendants certified that they would comply, and were in compliance, with Medicare laws and regulations by submitting Medicare Enrollment Form 855(A); claims for payment pursuant to CMS Form 1450 or UB-04; and "Annual Hospital Cost Reports," or form CMS 2252-10. (Doc. 1, ¶¶ 43-44). According to Relator, these laws and regulations include the TAVR NCD and § 1395y(a)(1)(A), which allow reimbursement for only reasonable and necessary medical services. (*Id.*). Relator claims that the UC Health defendants

failed to disclose that they were not in compliance with the volume requirements of the TAVR NCD when they submitted their claims for reimbursement, which made their representations that they were in compliance with all governing laws and regulations false. Assuming Relator strayed from this implied false certification theory in his opposing memorandum, the Court is not foreclosed from considering whether Relator has stated a claim for relief under the theory articulated in the complaint. The issue before the Court in connection with the UC Health defendants' motion to dismiss is whether Relator has stated a claim for relief under the FCA against them based on *some* valid legal theory. *See Griffith v. Conn*, No. CV 11-157, 2016 WL 1029331, at *1 (E.D. Ky. Mar. 14, 2016) ("To survive a motion to dismiss, any valid theory will do."). So long as Relator has stated a claim for relief in the complaint against the UC Health defendants under the FCA which withstands the defenses they have raised, his complaint against these defendants should not be dismissed. *Id.* at *2 (quoting *First Am. Title Co. v. Devaugh*, 480 F.3d 438, 444 (6th Cir. 2007)). The Court will therefore analyze whether Relator has stated a valid claim for relief under the FCA in light of the specific defenses raised by the UC Health defendants.

The UC Health defendants contend that under all three sections of the FCA upon which Relator relies - 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G) - his complaint fails to state a claim under the FCA. They argue that Relator has not—and cannot—establish that defendants knowingly submitted a false claim to the government because:

- His claims rely entirely on a non-binding guidance document, noncompliance with which cannot form the basis for liability under the FCA;

- He has not sufficiently alleged that defendants made any objectively false statement to the United States; and

- He has failed to sufficiently establish that any alleged non-compliance was material to the government's decision to pay a claim.

The Court addresses each of these defenses in turn.

ii. Compliance with the TAVR NCD

The UC Health defendants argue that Relator's complaint must be dismissed because NCDs, and more specifically the TAVR NCD, are simply guidance documents and noncompliance with them cannot give rise to liability under the FCA. (Doc. 10). Relator argues in response that NCDs are binding payment policies that govern whether a medical service was "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A); therefore, failure to comply with an NCD necessarily gives rise to FCA liability. (Doc. 16).

The UC Health defendants have not cited persuasive authority or made convincing arguments to support their restrictive view of NCDs and whether they can support liability under the FCA. They rely on several different authorities for their theory that the TAVR NCD is not a "duly promulgated regulation nor a statute" which supports the imposition of liability under the FCA but is "merely interpretative - a guidance document that is neither a statute nor a regulation promulgated under the administrative rulemaking process." (Doc. 10 at 3, 8, 13-14). However, none of these authorities support the propositions for which defendants cite them; that is, they do not show that an NCD is a "non-binding guidance document" that is insufficient, standing alone, to support the imposition of liability under FCA. (*Id.* at 14).

First, the UC Health defendants cite the Sixth Circuit's decision in *Chesbrough*, 655 F.3d at 467-68, for the proposition that "Medicare does not require compliance with an industry standard as a prerequisite to payment." (Doc. 10 at 14). Therefore, "requesting payment for tests that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA." (*Id.*). *Chesbrough* is distinguishable from this case. In *Chesbrough*, the plaintiffs alleged that the defendant "failed to meet 'objective

standards' for testing," but the plaintiffs did "not allege that [the defendant] was expressly required to comply with those standards as a prerequisite to payment of claims." *Id.* at 468. The plaintiffs in *Chesbrough* did not identify any "specific Medicare or Medicaid regulation that mention[ed] the standards" and only generally alleged that "Medicare regulations . . . only allow for reimbursement of indicated, appropriate diagnostic testing on Medicare beneficiaries." *Id.* Here, in contrast to *Chesbrough*, Relator alleges noncompliance with specific criteria in the TAVR NCD and, by extension, 42 U.S.C. § 1395y(a)(1)(A). Thus, *Chesbrough* does not support a finding that Relator's FCA claim cannot be premised on the TAVR NCD because it is a "non-binding guidance document."

Next, the UC Health defendants rely on a 2018 DOJ memorandum as support for their position that the TAVR NCD cannot support FCA liability. (Doc. 10 at 14, citing https://www.justice.gov/file/1028756/download). Defendants assert that according to the memorandum, the "DOJ cannot rely on guidance documents produced by agencies, like CMS, to presumptively or conclusively prove that a person violated a statute or regulation because 'agency guidance documents cannot create any additional legal obligations.'" (*Id.*). But defendants do not point to any language in the memorandum which supports characterizing the TAVR NCD as an "agency guidance document." (*Id.*). The DOJ memorandum therefore is not helpful in this context.

The UC Health defendants also cite the Justice Manual, Section 1-20.000, "Limitation on Use of Guidance Documents in Litigation," published in December 2018 to support their contention that the TAVR NCD is a non-binding guidance document. (Doc. 10 at 14-15, citing https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation). Defendants assert that Section 1-20.100 applies the 2018 DOJ memorandum to both civil and criminal

enforcement actions by DOJ employees. (*Id.* at 15). It states: "Criminal and civil enforcement actions brought by the [DOJ] must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulations." (*Id.* at 15, citing Justice Manual, Section 1-20.000). It also states: "The [DOJ] must establish a violation by reference to statutes and regulations [and] may not bring actions based solely on allegations of noncompliance with guidance documents." *Id.* But like the DOJ 2018 DOJ Memorandum, these provisions of the Justice Manual do not explain the meaning of the term "guidance documents." Further, defendants acknowledge these provisions of the Justice Manual set DOJ Policy and do not bind this Court. (*Id.* at 15, citing Justice Manual, Section 1-1.200). Thus, the Justice Manual does not shed any light on whether noncompliance with the TAVR NCD can support liability under the FCA.

Next, the UC Health defendants rely on the Sixth Circuit's decision in *Friedrich v. Sec'y of Health and Human Servs.,* 894 F.2d 829, 837-38 (6th Cir. 1990), as authority for the proposition that NCDs are non-binding guidance documents and to counter what defendants characterize as Relator's "impractical" and legally unsupported position that "any deviation from the Medicare guidance necessarily results in a false claim."[14] (Doc. 10 at 16). Defendants argue that "treating and reviewing physicians of a particular patient determine medical necessity" as defined by the American Medical Association and Medicare.gov[15] "because it is a matter of clinical judgment." (Doc. 10 at 16). Defendants characterize NCDs as "simply resources"

[14] The Court does not read Relator's position so broadly, nor is it necessary to address the validity of this purported argument. The issue before the Court is whether Relator has sufficiently pled FCA claims based on defendants' alleged failure to comply with the NCD on TAVRs.

[15] *See* Doc. 10 at 15-16 and 16 n.4, citing https://policyseach.ama- and https://www.medicare.gov/glossary/m.html.

produced by Medicare "[t]o assist in determining medical necessity" and to "offer interpretation and guidance on the medical necessity of certain procedures. . . ." (*Id.*). They assert that NCDS are "interpretative rules" which "simply state[] what the administrative agency thinks the statute means, and only remind[] affected parties of existing duties." (*Id.*, citing *Friedrich*, 894 F.2d at 834, 837-38). They contend that an NCD "creates no new law" but rather "interprets the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment" from the perspective of CMS. (*Id.*, citing *Friedrich*, 894 F.2d at 837). Defendants allege: "In other words, NCDs are not the last word on medical necessity." (*Id.*).

Defendants have not shown that *Friedrich* supports the dismissal of Relator's claims for relief in this case. *Friedrich* involved issues of administrative law and due process on appeal, specifically: (1) whether an NCD "is invalid if promulgated without compliance with the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.* (1982)"; and (2) "whether a hearing before an officer who is bound by such a determination violates due process." *Friedrich*, 894 F.2d at 830. The Court of Appeals held that the NCD barring Medicare payments for chelation therapy was not a legislative rule; it "create[d] no new law" but simply "interpret[ed] the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment." *Id.* at 837. Therefore, the NCD was not invalid for failure of the Secretary to comply with the requirements of the Administrative Procedure Act, 5 U.S.C. § 553(b). *Id.* at 837. The Court also found that there was "no basis for a legitimate claim of entitlement to this treatment." *Id.* at 838. Having generated an NCD, "the Secretary [was] not required to defend it in response to individual claims by every person who disagrees with the decision to deny coverage." *Id.* *Friedrich* did not address the question of whether an NCD can form the basis of a claim for relief under the FCA, and that conclusion does

not logically follow from the Court's holding. *Friedrich* does not support dismissal of Relator's FCA claims for relief against the UC Health defendants.

Finally, the UC Health defendants' contention that any noncompliance with the NCD does not give rise to an FCA violation because the NCD is not a binding law or regulation is at odds with existing caselaw. Courts have rejected the argument that NCDs are non-binding and cannot support an FCA claim. Those courts have reasoned that the determination of whether an individual treatment is "reasonable and necessary" under the Medicare statute, 42 U.S.C. § 1395y(a)(1)(A), is delegated in the first instance to the Secretary of HHS. Under the Medicare regulations, the Secretary's promulgation of an NCD "is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 CFR § 405.1060. Thus, "NCDs are considered substantive rules, which carry the force of law." *United States v. Adams*, 371 F. Supp. 3d 1195, 1212-13 (N.D. Ga. 2019) (quoting *Advanced Diabetes Treatment Ctrs., L.L.C. v. Sebelius*, Case No.: 09-61698, 2011 WL 13268857, at *4 (S.D. Fla. Apr. 7, 2011)). *See also United States ex rel. Dildine v. Pandya*, 389 F. Supp. 3d 1214, 1221 (N.D. Ga. 2019) ("Defendants thus cannot avoid liability by merely contending that NCDs are non-binding.").

Moreover, to hold otherwise would "effectively authorize [defendants] to violate [NCDs] but immunize [their] violations only because the terms of the [NCDs] are not included in a regulation or statute." *Cf. U.S. v. Kinetic Concepts, Inc.*, CV0801885, 2017 WL 2713730, at *7 (C.D. Cal. Mar. 6, 2017). Further, defendants' position is inconsistent with the well-reasoned decisions of many courts which have held that submission of a claim that does not comply with Local Coverage Decisions ("LCDs"), which are similar in nature to NCDs, can give rise to liability under the FCA. (*See* Doc. 16 at 8, citing *Druding v. Care Alternatives, Inc.*, 164 F.

Supp. 3d 621, 630 (D. N.J. 2016) (holding that claim was stated under the FCA based upon knowingly false records that had in some cases "included symptoms that fell short of the LCD's requirements for a terminal prognosis"); *United States v. Sklar,* 273 F. Supp. 3d 899, 900 (N.D. Ill. 2017) ("LCDs establish what is reasonable and necessary treatment for a procedure they cover, and [] submission of a claim that fails to conform to an applicable LCD constitutes a false claim"); *U.S. v. Kinetic Concepts, Inc.*, No. CV 08-01885, 2017 WL 2713730, *8 (C.D. Cal. Mar. 6, 2017) ("failure to comply with . . . LCDs may give rise to an FCA claim"); *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *5-*6 (E.D.N.Y. May 13, 2014) (court found that claims for procedure excluded by an LCD were false under the FCA). The district court in *Anesthesia Services Associates, PLLC*, 2019 WL 7372510, at *14, recently joined these courts and explained why an LCD can give rise to liability under the FCA:

> By statute, LCDs announce prospectively "whether or not a particular item or service is covered" by that contractor. 42 U.S.C. § 1395ff(f)(2)(B). The role of an LCD is essentially to interpret what Medicare would consider medically necessary and what documentation is needed to support reimbursement. Generally, "LCDs are mandatory for areas they cover." [*Lederman*, 2014 WL 1910096, at *5]; *see also United States v. Adams*, 371 F. Supp. 3d 1195, 1213 (N.D. Ga. 2019) (noting that, even though LCDs are not binding on the courts, courts give them "substantial deference where they apply"); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1012 (D. Nev. 2006) ("[LCDs] set regional coverage determinations that govern in the absence of or as an adjunct to a national policy." (citing 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003)). Several courts have held that noncompliance with LCDs may give rise to FCA liability. *See, e.g.*, *Adams*, 371 F. Supp. 3d at 1213; [*Sklar*, 273 F. Supp. 3d at 896]; *United States v. Space Coast Med. Assocs.*, LLP, 94 F. Supp. 3d 1250 (M.D. Fla, 2015); *Ryan*, 2014 WL 1910096 at *6.

Anesthesia Services Associates, PLLC, 2019 WL 7372510, at *14. The district court's reasoning is persuasive, and it applies with even greater force to NCDs, which have nationwide applicability.

The Court therefore concludes that noncompliance with an NCD can give rise to liability under the FCA, and the UC Health defendants' motion to dismiss on this basis should be rejected.

iii. The alleged need for an objective falsehood

The UC Health defendants argue that Relator has not stated a claim for relief under the FCA because Relator "never alleges that the UC Health Defendants actually submitted or caused to be submitted any false Claims to the government" as defined under 31 U.S.C. § 3729(b)(2)(A). (Doc. 10 at 17). They argue that "[a]t a minimum, the FCA requires proof of an objective falsehood." *Id.* (citing U.S. ex. rel. *Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000), *aff'd,* 302 F.3d 637 (6th Cir. 2002)). Defendants allege that Relator's claim is not "false" under the FCA because Relator does not allege defendants billed for services that were never provided, billed for fictitious patients, or billed based on forged or falsified documents. (Doc. 10 at 17).

Defendants have not cited any authority in support of their contention that an FCA claim must be premised on an "objective falsehood." Courts have rejected the argument that "a professional opinion as to medical necessity cannot be shown to be objectively false for purposes of stating a claim under the FCA." *Anesthesia Services Associates, PLLC*, 2019 WL 7372510, at *13 (citing *Adams*, 371 F. Supp. 3d at 1211 ("For purposes of this Order, the Court agrees with those courts that have concluded that a physician's subjective medical opinions or judgments can be false for purposes of the FCA. Defendants therefore are not entitled to dismissal based on this argument. Further, most of the cases that Defendants cite involve decisions on summary judgment."); *see also United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) ("It is possible for a medical judgment to be 'false or fraudulent' as proscribed by the

FCA."); *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 28 (D.D.C. 2017) ("[T]he Court cannot determine that the relator's allegations regarding medical necessity necessarily involve a difference of clinical judgment because to do so would require the Court to weigh the evidence, which is inappropriate at this stage of the litigation."), *amended on reconsideration in part*, 296 F. Supp. 3d 155 (D.D.C. 2017)).

Further, even assuming an objective falsehood were required to establish liability under the FCA, Relator has adequately alleged that the UC Health defendants made an objective misrepresentation. Relator alleges that the UC Health defendants violated the "volume requirements" of the TAVR NCD. The TAVR NCD provides in pertinent part as follows:

> A TAVR can only be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
>
> . . . .
>
> f. Appropriate volume requirements per the applicable qualifications [set forth in the NCD].

(*Id.*, ¶ 51). The volume requirements that health care entities without TAVR experience must meet to be eligible to bill for a TAVR procedure are:

> a. ≥ 50 total AVRs (Aortic Valve Replacements) in the previous year prior to TAVR, including ≥ 10 high-risk patients, and;
> b. ≥ 2 physicians with cardiac surgery privileges, and;
> c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

(Doc. 1, ¶ 54; Exh. 2). Relator alleges that the UC Health defendants had not performed the required number of AVR procedures before they began the TAVR program and billed Medicare for TAVR procedures. The number of procedures performed within a specified time frame appears to be an objective quantity, and a misrepresentation that the required number of procedures had been performed appears to an objective falsehood. Relator's complaint therefore

should not be dismissed on the ground he has not pled an objective falsehood. Whether Relator has plausibly alleged that the falsehood attributed to the UC Health defendants was material to the government's payment decision is a separate matter that is addressed *infra*.

iv. Whether the alleged misrepresentation was material

The UC Health defendants argue that Relator has failed to sufficiently establish that any alleged non-compliance was material to the government's decision to pay a claim. "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Prather II*, 892 F.3d 822, 831 (quoting *Escobar*, 136 S. Ct. at 2002). Factors relevant to whether an alleged misrepresentation was material to the government payment decision include: (1) "the Government's decision to expressly identify a provision as a condition of payment"; (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or whether, with actual knowledge of the non-compliance, the government consistently pays such claims and there is no indication that its practice will change; and (3) whether the "noncompliance is minor or insubstantial" or whether it goes "to the very essence of the bargain." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003 & n.5). The list of factors is not exclusive, and no one factor is dispositive. *Id.* (quoting *Escobar*, 136 S. Ct. at 2001-04).

The first factor relevant to materiality is whether the government has expressly designated the provision that the defendant allegedly violated as a "condition of payment." *Id.* Defendants can be liable under the FCA for violating requirements even if they were not expressly designated as conditions of payment, but it does not follow that every violation of a requirement expressly designated a condition of payment gives rise to liability. *Escobar*, 136 S.

Ct. at 2001. "[T]he government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2003.

The second factor relevant to the materiality inquiry is whether there is "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," which is evidence of materiality. *Id.* at 2003. Conversely, evidence that "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated" is "very strong evidence that those requirements are not material." *Id.* Similarly, evidence that "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position," is "strong evidence that those requirements are not material." *Id.* at 2003-04. A relator is "not required to make allegations regarding past government action" at the pleading stage to survive a motion to dismiss. *Prather II*, 892 F.3d at 834. If there are no "allegations regarding past government action taken in response to known noncompliance with [a regulation]," the government's payment history provides no support for the conclusion that a requirement is material. *Id.* at 833-34.

A third consideration is whether "non-compliance is minor or insubstantial" or if it goes "to the very essence of the bargain." *Escobar*, 136 S. Ct. at 2003 & n.5.

The UC Health defendants allege that Relator has not made sufficiently detailed and plausible factual allegations to show that CMS would not have reimbursed defendants for TAVR procedures had CMS known of defendants' alleged non-compliance with the TAVR NCD. They contend that at most, Relator has alleged that the United States "may be entitled to decline

payment based on the alleged noncompliance," which is insufficient to satisfy Relator's pleading burden under *Escobar*, 136 S. Ct. at 2002-03. (Doc. 10 at 18-19).

Relator has adequately alleged that the UC Health defendants' false certification of compliance with the TAVR NCD volume requirements was a factor material to the Government's payment decision. The complaint alleges that the UC Health defendants' claims are fraudulent because they failed to satisfy the NCD conditions for coverage of TAVR procedures. Specifically, Relator alleges that defendants did not perform the required number of AVR procedures, and their heart team had not acquired the required experience, before they began performing and billing the Government for TAVR procedures. Thus, in determining materiality, the relevant question is whether the volume requirements of the TAVR NCD were "condition[s] of payment" under the first *Escobar* factor. 136 S. Ct. at 2003 & n.5.

The TAVR NCD premises the condition of payment on the "reasonable and necessary" requirement of § 1395y(a)(1)(A). (Doc. 1, Exh. 2 at 68). Section 1395y(a)(1)(A) specifies when payment will not be authorized under Medicare: "*no payment* may be made under part A or part B for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (emphasis added). The NCD manual, which contains the "determination by the Secretary of whether a particular item or service is covered nationally under Medicare," 42 CFR § 405.1060, "describes whether specific medical items, services, treatment procedures, or technologies *can be paid for* under Medicare." (Doc. 1, Ex. 2 at 68) (emphasis added). As it relates to this case, the NCD manual provides, "Where an item/service is stated to be covered, *but such coverage is explicitly limited to specified indications or specified circumstances*, all

limitations on coverage . . . are based on § 1862(a)(1) of the Act," i.e., the "not reasonable and necessary" exclusion set forth in 42 U.S.C. § 1395y(a)(1). (*Id.*).

The TAVR NCD indicates that "coverage [for TAVR procedures] is explicitly limited to specified indications or specified circumstances." (*Id.*). Section 20.32 of the TAVR NCD states, in pertinent part, "TAVR is covered . . . when *all* of the following conditions are met," including the "[a]ppropriate volume requirements per the applicable qualifications. . . ." (Doc. 1 at 70) (emphasis added); (Doc. 1, Exh. 2). The NCD then sets out "Qualifications to begin a TAVR program for hospitals without TAVR experience" and the qualification the hospital program "must have." (*Id.*). The NCD expressly conditions payment for TAVR procedures on compliance with "all" of the conditions set forth in Section 20.32. The prefatory language of Section 20.32 specifying that "all" conditions must be met as an express condition of TAVR coverage under the "reasonable and necessary" provision of the Medicare Act is a strong indication that the volume requirement is "condition of payment" for TAVR procedures under Medicare. The "condition of payment" factor supports a finding that the UC Health defendants' alleged failure to comply with the volume requirements of the TAVR NCD was material to the government's payment decision.

The language in the TAVR NCD is comparable to the direct language in other Medicare requirements that have been held to create conditions of payment. *See, e.g., U.S. ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019). For example, in *Lemon,* the Court found that certifications required under § 1395f(a)(7) are "'conditions of . . . payment for' hospice services":

> Specifically, § 1395f(a)(7) provides that "payment for services furnished" may be made "only if" the certification, face-to-face encounter, and plan-of-care requirements are made. Moreover, Medicare regulations for hospice services state that "to be covered," certifications regarding terminal illness must be completed. .

> . . These regulations also condition coverage (or eligibility) of a patient to receive any Medicare hospice service on certification by the provider of a terminal illness.

Id. at 161 (footnotes omitted).

Like the Medicare statute in *Lemon*, 42 U.S.C. § 1395y(a)(1) specifies that "no payment will be made" for services or procedures that are "not reasonable and necessary." The TAVR NCD conditions coverage, i.e., eligibility for payment, on meeting "all" of the requirements, including the volume requirements, of the NCD. Therefore, the first *Escobar* factor weighs in favor of a finding of materiality in this case.

The second *Escobar* factor, whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or whether, with actual knowledge of the non-compliance, the government consistently pays such claims and there is no indication that its practice will change, is neutral. 136 S. Ct. at 2003 & n.5. Relator has alleged that the United States would not have paid the UC Health defendants' claims had it known about defendants' alleged failure to comply with the TAVR NCD. However, there is no allegation that the Government had actual knowledge of defendants' alleged non-compliance. Therefore, the Government's past action in response to similar claim submissions has no relevance to the materiality inquiry at the motion to dismiss stage. *See Prather II*, 892 F.3d at 834 ("Although a relator in a *qui tam* action faces a demanding standard at the motion-to-dismiss stage with respect to pleading materiality, []he is not required to make allegations regarding past government action.").

The third *Escobar* factor, whether the "noncompliance is minor or insubstantial" or whether it goes "to the very essence of the bargain," 136 S. Ct. at 2003 & n.5, weighs in favor of a finding of materiality. Relator argues that the UC Health defendants breached the benefit of their bargain with the Government by submitting claims for payment for services that were not

reasonable and necessary. (Doc. 16 at 18). Relator relies on § 1395y(a)(1)(A) to argue that the claims for TAVR relate to an agreement that the UC Health defendants would bill the United States only for services that were reasonable and necessary, and the Government would pay for only those services that were consistent with its statutory and regulatory parameters. (Doc. 16 at 18, citing Doc. 1, ¶ 80; *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018), *cert. dismissed sub nom. Intermountain Health v. U.S. ex rel. Polukoff*, 139 S. Ct. 2690 (2019)). The alleged misrepresentation at the heart of Relator's fraud claims is that the UC Health defendants began a TAVR program and billed the Government for TAVR procedures without meeting the volume requirements of the TAVR NCD. The issue underlying Relator's FCA claims against the UC Health defendants is whether the payments the UC Health defendants received were based on those volume requirements, or whether the requirements were minor or insubstantial qualifications that were not material to the government's decision to pay the claims. Relator has plausibly alleged that the volume requirements were a basis for those payments.

The TAVR NCD specifies that TAVR procedures are covered by Medicare "when *all* of the following conditions are met." (Doc. 1, Ex. 2 at 69) (emphasis added). Those conditions include that "TAVR *must* be furnished in a hospital with the appropriate infrastructure that includes but is not limited to: . . . f. Appropriate volume requirements per the applicable qualifications below." (*Id.* at 70). These qualifications set forth the volume requirements for both hospital programs and physician heart teams "without previous TAVR experience" and "those with TAVR experience." (*Id.*). Those programs and heart teams without previous TAVR experience "must" have performed a minimum number of AVR procedures within the previous year on a specified number of high-risk patients before TAVR procedures will be covered by

Medicare. (*Id.*). Even where a hospital or heart team has previous TAVR experience, the program or heart team "must" maintain specified numbers of AVRs per year, among other requirements, to be covered for TAVR procedures. (*Id.* at 71). The volume requirements are detailed and specific, and the mandatory language of the TAVR NCD indicates these requirements must be met before TAVR procedures will be covered by Medicare. These volume requirements go to the very essence of approving a hospital program or heart team for payment of TAVR procedures under Medicare. This factor weighs in favor of a finding of materiality.

Relator has plausibly alleged that the government would not have paid the UC Health defendants' claims for reimbursement for TAVR fees and services if the government had known that defendants were not in compliance with the TAVR NCD. The specific limitations and circumstances set forth in the TAVR NCD are based on the "not reasonable and necessary" language of the Medicare statute. (Doc. 1, ex. 2 at 68). In other words, where specified circumstances are not satisfied, i.e., where the volume requirements for covering TAVR are not met, Medicare payments for TAVR procedures are "not reasonable and necessary" under § 1395y(a)(1)(A). Construing the facts in the light most favorable to Relator and accepting as true Relator's allegations that the UC Health defendants violated the volume requirements of the TAVR NCD, Relator has plausibly alleged that the misrepresentations the UC Health defendants made about their compliance with those requirements were material to the government's payment decision. The UC Health defendants' motion to dismiss on this basis should be denied.

2. University of Cincinnati Physicians, Inc. (UCP)'s motions to dismiss (Docs. 17, 25)

Defendant UCP filed a motion to dismiss the original complaint on July 22, 2019. (Doc. 17). Relator subsequently filed his amended complaint on August 12, 2019. (Doc. 20). UCP then moved to dismiss the amended complaint on September 9, 2019 under Fed. R. Civ. P. 8,

12(b)(6), and 9(b). (Doc. 25). Defendant UCP moves to dismiss Relator's FCA claims against it, asserting that: (1) Relator has improperly named UCP as a party to the action; (2) Relator has not satisfied the "presentment" pleading requirement as to UCP; (3) Relator has not satisfied the "scienter" pleading requirement as to UCP; and (4) Relator has not pled his claims with the required "particularity" as to UCP. (Docs. 25, 38).

In support of its motion to dismiss the amended complaint, UCP adopts the arguments made by the UC Health defendants in their motion to dismiss the original complaint (*See* Doc. 10) and argues that the amendment has not cured the factual and legal deficiencies in the original complaint. (Doc. 25).[16] UCP asserts that the amended complaint does little more than substitute allegations that UCP "caused to be submitted" certain claims for billing by other parties for his allegations that UCP "submitted" a false claim; however, UCP contends that the amended complaint does not link these amended allegations against UCP to any specific false claim. (*Id.* at 2). Defendant UCP also argues that the only new claim Relator raised against all defendants named in the amended complaint - a claim of conspiracy to obtain payments for false claims (Doc. 20, ¶ 110) - is contradicted by other allegations in the amended complaint and lacks the "required specificity as to the actions of UCP." (Doc. 25 at 2). UCP argues that Relator's claims against UCP under 31 U.S.C. §3729(a)(1)(A) and (B) must be dismissed because Relator has not specifically alleged that UCP presented, or caused to be presented, a claim for payment or approval to the Government, and Relator has not alleged sufficient facts to support his claim that "UCP knowingly made, used, or caused to be made or used, a record or statement material to a claim." (*Id.* at 3). UCP further argues that Relator's claim under § 3729(a)(1)(C) against UCP

[16] To the extent UCP joins in the motion to dismiss filed by the UC Health defendants, for the reasons set forth above, the Amended Complaint as to UCP should not be dismissed.

must be dismissed because Relator has not set forth sufficient facts to show that UCP "engaged in any conspiracy to submit a false claim." (*Id.* at 4).

Relator filed a response to UCP's motion to dismiss the amended complaint on October 21, 2019. (Doc. 34). Defendant UCP filed a reply in support of the motion on November 21, 2019. (Doc. 38). Because UCP filed a responsive pleading to the amended complaint which is fully briefed, the Court will consider UCP's motion to dismiss the complaint as amended and recommend that its motion to dismiss the original complaint (Doc. 17) be denied as moot.

A. Allegations of the amended complaint (Doc. 20)

Relator makes the following allegations in the amended complaint which are relevant to Relator's claims against defendant UCP: Defendant UCP is an Ohio corporation and Relator's employer. (Doc. 20, ¶ 13). UCP employs physicians and leases those physicians and other employees to defendant UC Physicians, an Ohio not for profit limited liability company of which UC Health is the sole member. (*Id.*, ¶¶ 13, 14). According to the UC Health defendants, UC Physicians submitted the false claims at issue in this case to the Government. (*Id.*, ¶ 14).

Defendants UCMC, UC Health, UCP, and UC Physicians are "Medicare providers [who] are required to enter into provider agreements with the federal government." (Doc. 20, ¶ 28). Defendants "certified in their various billing statements and provider agreements that they had complied with Medicare laws, regulations, and the FCA and that all of the claims presented for medical services that were rendered by the parties were reasonable and necessary." (*Id.*, ¶ 39). This certification was a "prerequisite" for hospitals, physicians, and their corporate entities to obtain payments from federal health care programs. (*Id.*, ¶ 40). UCP submitted CMS 1500 forms to the Medicare contractor when seeking reimbursement for services provided to Medicare patients, and in doing so, UCP "certified that the medical services its physicians were providing

to the patients they were treating were medically necessary." (*Id.*, ¶¶ 52, 80). Defendant UCP is also bound by the requirements of the TAVR NCD. (*Id.*, ¶ 62).

Dr. Shreenivas joined UCMC, UCP, UC Health, and UC Physicians in 2014. (*Id.*, ¶ 64). From December 14, 2015 through August 21, 2017, Dr. Shreenivas and Dr. Imar Arif, both UCP physicians, performed 33 TAVR procedures at UCMC. (*Id.*, ¶ 77). At least 12 of the procedures "were billed" to Medicare, Medicaid, and the Veterans Administration - TriCare/Champus. (*Id.*) Since August of 2017, 21 additional TAVR procedures have been performed by Dr. Arif of UCP at UCMC and "billed or caused to be billed by UC Physicians to the United States." (*Id.*, ¶ 78). Relator alleges that, "[e]ach of the 33 similar TAVR procedures billed to Medicare, Medicaid or Champus did not meet the applicable NCD for TAVR procedures required under federal law." (*Id.*, ¶ 78).

Relator alleges that Dr. Shreenivas gave prior notice to defendants that "UCMC and UC Health did not qualify under the applicable NCD to bill a government health benefits program for TAVR procedures because UCMC had not performed at least 50 AVRs within the prior year." (*Id.*, ¶ 66). Relator alleges that Dr. Shreenivas gave this notice via email to and a subsequent conversation with Dr. Richard Becker, "Chief of the Division of Cardiovascular Health & Disease for the Heart, Lung & Vascular Institute" and "Director of the Heart Lung and Vascular Institute." (*Id.*). Dr. Shreenivas also asked that UCMC's failure to achieve the minimum number of AVRs be reviewed by UCMC's legal department. (*Id.*). On November 1, 2015, Dr. Shreenivas asked two cardiac surgeons at UCMC, Dr. Louis and Dr. Alan Simeone, whether there were any other patients on whom they had performed AVRs "in order to confirm that UCMC had reached the minimal number of AVRs to allow UCMC, UCP, and UC Health to

bill a government medical benefit program for the TAVR procedures." (*Id.*, ¶ 67; Exh. 6). No additional information was received in response to his inquiry. (*Id.*).

On November 16, 2015, UCMC issued a status report that UCMC was ready to begin TAVR procedures within its Structural Heart Program starting on December 15, 2015. (*Id.*, ¶ 68; Exh. 7, p. 4). The status report confirmed that the rolling total of AVRs for the prior year was 26. (*Id.*). The first anticipated TAVR patient was a VA patient and the next three patients were Medicare patients. (*Id.*).

Relator alleges that before any billings for TAVRs were submitted to a government sponsored benefits program, "Dr. Shreenivas again informed UCMC, UCP, UC Health, and UC Physicians that billing for these procedures was unlawful." (*Id.*, ¶ 69). Relator alleges that the notice was provided (1) via email communications related to Dr. Shreenivas' failure to complete the "OP" note for Patient RTMR04040680, and (2) through conversations concerning the illegality of "billing government sponsored health care programs for TAVR procedures when the NCD prerequisites had not been met for AVR volume. . . ." (*Id.*, ¶¶ 69-75). Relator alleges that on January 25, 2016, Jaime Hamm, the billing coordinator for UC Health, UCMC, and UCP, wrote to Dr. Shreenivas "to indicate that an inpatient account for RT MR 04020680" had not yet been billed to Medicare due to Dr. Shreenivas' failure to complete the OP note. (*Id.*, ¶ 69, Exh. 8). Relator alleges that because "Dr. Shreenivas believed billing Medicare" for the TAVR procedure was illegal, he had not completed the OP note by February 1, 2016. (*Id.*, ¶ 70). This led UCMC's Medical Director, Dr. Naber, to ask Peter Clayton, "Executive Director for Business Affairs at the University of Cincinnati for UC Health and UCP," to "help with the dictation." (*Id.*; Exh. 8, p. 2). Clayton asked Dr. Shreenivas to "[p]lease complete your dictation on - - or advise on difficulties." (*Id.*, Exh. 8, p. 1). Dr. Shreenivas responded that the

patient account "cannot be billed" and asked Clayton to call him to discuss. (*Id.*, ¶ 71, Exh. 8, p. 1). Dr. Naber wrote in an email to Dr. Shreenivas and Clayton dated February 3, 2016: "I have talked to Craig Cain about this case, he was peripherally aware. We will be billing only Medicare (not the patient) so we still need the dictation to do this properly. Thanks for all your help clarifying this delicate situation." (*Id.*, ¶ 72; Exh. 8, p. 1).

Dr. Shreenivas subsequently wrote to Rhonda Schlesinger, the billing code manager for UCMC, UCP, UC Health, and UC Physicians, on August 25, 2016, to inquire about the billing status of his TAVR patients. (*Id.*, ¶ 73). In response, she sent a TAVR case log that indicated the payment status for all TAVR patients. (*Id.*, ¶¶ 74, 77-78).

Relator alleges that he is aware that a member of UCMC's medical staff and a former employee of UCP, Dr. Tom Smith, told UCMC and UCP officials that billing the Government for TAVR procedures when the NCD volume requirements had not been met was unlawful. (*Id.*, ¶ 75). Relator alleges this information was conveyed to Dr. Charles Hattemer, the Associate Chief of Clinical Affairs at UCMC and a member of UCP. (*Id.*). Relator alleges that Dr. Shreenivas and Dr. Smith ceased their employment with UCP because they were concerned, in part, about UCMC, UCP, and UC Health's unlawful conduct. (*Id.*, ¶ 76).

Dr. Shreenivas and Dr. Arif performed the TAVR procedures listed in ¶ 77. (*Id.*, ¶ 77). Dr. Arif of UCP performed the 21 additional TAVR procedures listed in ¶ 78. (*Id.*, ¶ 78). Relator alleges that UCMC, UCP, UC Health, and UC Physicians "presented or caused to be presented claims for reimbursement relating to NCDs and TAVR procedures that did not meet [the TAVR NCD] criteria for payment." (*Id.*, ¶ 54). Relator alleges that UCP was aware prior to the submission of claims for Part B professional services that "the minimum prerequisite volume of AVRs in the prior year as mandated" in the TAVR NCD had not been met and that "any

request for reimbursement of the Part B professional expenses for medical services relating to the TAVR procedures is not reasonable or necessary under federal law." (*Id.*, ¶¶ 82, 85). Relator alleges that notwithstanding this knowledge, UCP "knowingly submitted or caused to be submitted" to the government Part B professional fees for reimbursement that were not reasonable and necessary under § 1395y(a)(1)(A) because they violated the TAVR NCD. (*Id.*, ¶¶ 83, 86).

Relator identifies the essential pleading components of his fraud claim by alleging that the four defendants named in the amended complaint are "who" committed the fraud. (*Id.*, ¶ 94). He identifies "when" the fraud was allegedly committed as the period from 2015 to 2018. (*Id.*, ¶ 95). Relator alleges that "what" occurred are the TAVR procedures identified by CPT Codes 33361 and 33362, which designate TAVR procedures. (*Id.*, ¶ 96). Relator alleges that "where" is shown by ¶¶ 77-78, which list "claims that were presented or caused to be presented to the VA, CareSource, and Medicare." (*Id.*, ¶ 97). Finally, as to "how" the claims were submitted, Relator alleges that UCMC and UC Health submitted claims for Part A facility fees related to CPT Codes 33361 and 33362, and UCP and UC Physicians submitted false claims for Part B professional fees in violation of the "various provider agreements" defendants executed with the United States. (*Id.*, ¶ 98).

Relator claims that defendants UCMC, UCP, UC Health, and UC Physicians violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented false claims for payment of fees for TAVR procedures to federally funded health insurance programs. (*Id.*, ¶¶ 99-100). Relator alleges that defendants had falsely certified prior to submitting the claims that they had complied with federal laws, which was untrue, and the false representations were material to the Government's decision to pay the claims. (*Id.*, ¶¶ 101-102).

Relator also claims that defendants UCMC, UCP, UC Health, and UC Physicians violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be used false or fraudulent records or statements or statements material to a false statement to the United States for the purpose of having a false or fraudulent TAVR claim paid or approved. (*Id.*, ¶¶ 103-104). Relator alleges that the representations were material to the United States's decision to pay the claims, and the United States was unaware of the truth or falsity of the claims or statements made and paid for the procedures in reliance on the accuracy of the claims. (*Id.*, ¶¶ 105-06).

Relator also brings a claim under 31 U.S.C. § 3729(a)(1)(C), alleging that UC Health owns and operates UCMC, UCP, and UC Physicians, and that executives of these four entities conspired among themselves "in a single plan" to submit or cause to be submitted false claims to the United States for payments for TAVR procedures that "violated the applicable" NCD, such that "reimbursement for these procedures were not reasonable or necessary under federal law." (*Id.*, ¶¶ 108-109). Relator alleges that all defendants "shared in the general conspiratorial objective to get these false claims paid." (*Id.*, ¶ 110). Relator also alleges that "[a]t least one or more of the conspirators[,] including UC Physicians[,] performed the act in submitting the false claim in furtherance of a conspiracy in order to get the claims identified in paragraphs 77 and 78 paid." (*Id.*, ¶ 110).

B. Requirement to plead fraud with particularity as to UCP

The amended complaint must satisfy Fed. R. Civ. P. 9(b)'s pleading standard to survive defendant UCP's motion to dismiss. Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The heightened pleading standard is designed to "alert defendants 'as to the

particulars of their alleged misconduct' so that they may respond," *Chesbrough*, 655 F3d at 466 (quoting *Bledsoe II*, 501 F.3d at 503); "prevent 'fishing expeditions,'" *Id.* (quoting *Bledsoe II*, 501 F.3d at 503 n.11); "protect defendants' reputations from allegations of fraud," *Id.*; and "narrow potentially wide-ranging discovery to relevant matters." *Id.* at 466-67 (citing *United States ex rel. SNAPP, Inc. v. Ford Motor Company,* 532 F.3d 496, 504 (6th Cir. 2008) ("*SNAPP I*")). To achieve these purposes, Relator "must 'allege the time, place, and content of the alleged misrepresentation on which [the Government] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.'" *Marlar,* 525 F.3d at 444 (quoting *Bledsoe I*, 342 F.3d at 643). In addition, in a case where the relator "alleges a complex and far-reaching fraudulent scheme," the complaint must "also identify a representative false claim that was actually submitted to the government." *Prather I,* 838 F.3d at 768 (internal quotations omitted) (citing *Chesbrough*, 655 F.3d at 470 (quoting *Bledsoe II*, 501 F.3d at 510)). "Although the relator does not need to identify *every* false claim submitted for payment, []he must identify with specificity 'characteristic examples that are illustrative of the class of all claims covered by the fraudulent scheme.'" *Id.* (quoting *Chesbrough*, 655 F.3d at 470) (in turn quoting *Bledsoe II*, 501 F.3d at 511).

Defendant UCP argues that Relator has not satisfied the pleading requirements of an FCA claim by specifying, at a minimum, the "who, what, when, where, and how" of the alleged fraud. (Doc. 25 at 11, quoting *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006)). UCP also asserts that Relator has not pled specific facts that show the time, place and content of any alleged misrepresentation, the fraudulent scheme, and the manner in which the false statements or scheme induced the Government to pay a claim to the defendant. (*Id.*, citing *SNAPP I,* 532 F.3d at 504; *see also Chesbrough,* 655 F.3d at 467). UCP contends that Relator

makes only "broad, sweeping" allegations throughout the complaint, which group the UC Health defendants and UCP together, and which therefore lack the required specificity needed to plead fraud under the FCA. (*Id.* at 4). UCP contends that Relator's general allegations that a group of defendants allegedly submitted claims do not satisfy the heightened pleading requirements of Rule 9(b). (*Id.* at 11, citing *Bledsoe I*, 342 F.3d at 643). UCP avers that Relator has not alleged that UCP engaged in any specific conduct that gives rise to FCA liability, but instead Relator has simply "lumped" all the defendants together. (*Id.* at 12).

1. Presentment

Defendant UCP focuses its arguments in its motion to dismiss on the "presentment" and "scienter" elements of an FCA claim. First, UCP contends that Relator has not adequately alleged that UCP "knowingly presented or caused to be presented a claim for payment to the federal government." (*Id.* at 9, citing Doc. 20, ¶¶ 93-98). UCP contends that Relator alleges a complex and far-reaching fraudulent scheme under 31 U.S.C. § 3729(a)(1), so that Relator must meet the "stringent" pleading requirements of the statute. (*Id.* at 8-9, citing *Marlar,* 525 F.3d at 445). That is, Relator cannot simply plead a scheme; he must also identify a representative false claim that was presented to the government. *Id.* (citing *Chesbrough*, 655 F.3d at 470; *Ibanez*, 874 F.3d 905).

UCP contends that Relator has not carried his burden here by identifying a false claim that UCP knowingly submitted to the Government for payment. (*Id.*, citing *U.S. ex rel. Eberhard v. Physicians Choice Laboratory Servs., LLC*, 642 F. App'x 547 (6th Cir. 2016)). UCP acknowledges that the amended complaint identifies invoice and medical record numbers for TAVR procedures that were "allegedly performed at UCMC and billed to the federal health care programs by UC Physicians." (*Id.* at 9, citing ¶¶ 77-78). UCP also notes that Relator

indicates in the amended complaint that he has a document produced by UCMC which identifies these patients. (*Id.*). However, UCP contends there is no allegation that UCP was the entity who submitted these claims for payment. (*Id.* at 9, citing *U.S. ex rel. Kustom Prods. v. Hupp & Assocs.*, No. 2:15-cv-03101, 2017 WL 2021512, at *1 (S.D. Ohio May 12, 2017) (dismissing FCA complaint that failed "to identify the specific claims that were submitted to the United States"); *Chesbrough*, 655 F.3d at 472 (noting there is a "strict requirement that relators identify actual false claims")). UCP contends that Relator makes only blanket references to acts or omissions by all defendants, which do not apprise UCP of the "circumstances surrounding the fraudulent conduct with which [it] individually stands charged." (*Id.* at 11-12, quoting *Bledsoe*, 342 F.3d 634, 643; *see also U.S. v. Kreipke v. Wayne State University*, No. 12-14836, 2014 WL 6085704, at *10 (E.D. Mich. No. 13, 2014) (relator did not satisfy pleading requirements by alleging only "very generally that the '[d]efendants' engaged in fraudulent activity")). UCP argues that, "absent any allegations of a representative false claim actually submitted to the federal government by UCP, Relator's claim under § 3729(a)(1)(A) fails." (*Id.* at 9).

Relator argues in response that he is not required to attach a copy of a claim to his FCA complaint to satisfy Rule 9(b); instead, he need only plead facts that are sufficient to support a "strong inference" that a claim was submitted. (Doc. 34 at 44, citing *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522, 527 (M.D. Pa. 2008)). Relator alleges that he has pled sufficient facts by identifying the fraudulent scheme; the defendants and their agents' knowledge of the scheme; the specific patients who underwent the TAVR procedures; when the TAVR procedures were performed; and each defendant's submission of a request for payment to the Government for Part A facility fees and Part B professional fees. (*Id.* at 44). Relator contends he is not required to do more and attach some, or even all of the false claims that were

submitted to the government, because he alleges the claims are all false for the same reason: i.e., "each claim submitted by UCMC, UC Health, and UCP are [sic] false because there were insufficient number of procedures performed by the Defendants as a prerequisite before billing the United States for a TAVR procedure." (*Id.*). Relator argues that because there is nothing unique about the individual claims in issue, the purposes of Rule 9(b) would not be served by the requirement that he submit an actual claim to the Court. (*Id.*; *see Repko,* 557 F. Supp. 2d at 527 (although the relator is generally required to submit to the court some or all of the allegedly fraudulent claims, it was not necessary in that case where the relator alleged that every claim was false because it was the result of an allegedly illegal referral under applicable laws)).

Relator contends that UCP's argument to the contrary relies in large part on *Chesbrough*, 655 F.3d 461, and *Bledsoe II*, 501 F.3d at 502, which Relator asserts are distinguishable from this case. Relator contends that the Sixth Circuit held in both cases that "under certain circumstances, the 'actual false claim rule' may be relaxed." (Doc. 34 at 45-46, citing *Chesbrough*, 655 F.3d at 470 (quoting *Bledsoe II*, 501 F.3d at 504, n.12)). Relator further contends that the Sixth Circuit has held following these decisions that the "relaxed" actual false claim rule applies where the relator has alleged facts which supports a "strong inference that a false claim had been submitted." (Doc. 34 at 46-47, citing *Chesbrough*, 655 F.3d at 471; *Prather I*, 838 F.3d 750). Relator alleges that following these decisions, "district courts have recognized that an actual false claim is not required in order to meet Rule 9(b)." (*Id.* at 46-50, citing cases).[17] Relator contends he has satisfied the required standard and shown a "strong inference"

[17] Relator cites the following decisions to support its position: *United States ex rel. Elliott v. Brickman Group, Ltd., LLC*, Case No. 1:10-cv-392 (S.D. Ohio Aug. 25, 2011) (Barrett, J.); *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, No. 2:08-cv-00114, 2012 U.S. Dist. LEXIS 48026 at ¶¶ 24-31 (S.D. Ohio Feb. 27, 2012) (Marbley, J.); *United States ex rel. Daughtery v. Bostwick Laboratories, et al.*, No. 1:08-cv-00354, 2012 Dist LEXIS 178641 at 38 (S.D. Ohio Dec. 18, 2012) (Spiegel, J.); *United States ex rel. Meyer v. Kempf Surgical Appliances*, No. 1:11-cv-00111, 2013 Dist. LEXIS 50962 at ¶¶ 9-10 (S.D. Ohio Apr. 9, 2013) (Spiegel, J.); *United States ex rel.*

that a false claim was submitted by providing a log showing the patient information, date of service, amount, and payment status for all TAVR billings presented to government health care programs for payment during the relevant period. (Doc. 34 at 50, citing Doc. 20 at 34).

The Sixth Circuit has not broadly endorsed a "relaxed" pleading standard in FCA cases, but it has applied that standard when the circumstances warrant. In *Bledsoe II*, the Court did not apply the exception but simply stated in dicta that it may be possible for a court to "relax[]" the rule that the relator must "identify with particularity any actual false claims" that the defendants submitted to the government "in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator." *Id.* at 504 n.12. In *Chesbrough,* 655 F.3d at 471, the Sixth Circuit acknowledged the possibility that a "'relaxed' version of Rule(b)" may apply "in certain situations." The Court found that the case law "suggests that the requirement that a relator identify an actual false claim may be relaxed when, even though the relator is unable to produce an actual billing or invoice, he or she has pled facts which support a strong inference that a claim was submitted." *Id.* The Court explained that "[s]uch an inference may arise when the relator has 'personal knowledge that the claims were submitted by Defendants . . . for payment." *Id.* (quoting *United States ex rel. Lane v. Murfreesboro Dermatology Clinic, PLC,* No. 4:07-cv-004, 2010 WL 1926131 (E.D. Tenn. May 12, 2010); *see also Marlar,* 525 F.3d at 446; *Hill v. Morehouse Med. Associates, Inc.,* No. 02-14429, 2003 WL 22019936 (11th Cir. Aug. 15, 2003)). However, the court found that was not the situation in the case before it. The relators in *Chesbrough* had no personal knowledge of

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Hollman v. Millennium Radiology, Inc., et al., No. 1:11-cv-00825, 2014 Dist LEXIS 138549 at ¶ 24 (S.D. Ohio Sept 30, 2014) (Barrett, J.).

billing practices or contracts with the government; instead, their personal knowledge was "limited to the allegedly fraudulent scheme." *Id.* at 472. Further, the relators did not allege other facts that made it "highly likely that a claim was submitted to the government for payment." *Id.* at 472. Rather, the Court explained that "[t]o conclude that a claim was presented requires a series of assumptions," including that the tests were performed on Medicare or Medicaid patients, and could therefore have been billed to the government; that the defendant submitted bills for useless tests; and that the defendant, as a for-profit company, must have billed for the services it performed rather than absorbing the cost of the nondiagnostic tests at issue. *Id.* The Court found that considering the need to draw these assumptions, the situation was not one "in which the alleged facts support a strong inference - rather than simply a possibility - that a false claim was presented to the government." *Id.* The Court concluded:

> In *Bledsoe, Sanderson,* and *Marlar,* we imposed a strict requirement that relators identify actual false claims. The Chesbroughs have no personal knowledge that claims for nondiagnostic tests were presented to the government, nor do they allege facts that strongly support an inference that such billings were submitted. We therefore conclude that the Chesbroughs' complaint fails to satisfy Rule 9(b).

Id.

The Sixth Circuit subsequently identified circumstances warranting the Court to "relax" the requirement to "identify with particularity any actual false claims" presented to the government for payment in *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750 (6th Cir. 2016) (*Prather I*). In *Prather I*, the relator did not allege facts indicating the actual submission of a specific request for anticipated payment to the government. However, even though the relator was unable to produce an actual billing or invoice, she had pled facts supporting a strong inference that a claim was submitted. This included a detailed overview of the alleged fraudulent scheme; sufficient knowledge of the

defendant's billing processes and claims submission; responsibilities that included working through a backlog of Medicare claims for compliance with state and federal insurance requirements in anticipation of them being submitted to Medicare; and the provision of other information, such as dates on which the physician certification of need and face-to-face documentation were signed. *Prather I*, 838 F.3d at 769-70. Under these circumstances, the Sixth Circuit found the relator's "detailed knowledge of the billing and treatment documentation related to the submission of requests for final payment, combined with her specific allegations regarding requests for anticipated payment" created a "strong inference that the specific documentation that [the relator] reviewed related to patients for whom requests for anticipated payment had been submitted to the government for payment." *Id.* at 770.

Here, Relator has alleged facts strongly suggesting that "actual false claims [] in all likelihood exist" and have been presented to the Government for payment by UCP. *See Bledsoe II*, 501 F.3d at 504 n.12. Relator has identified specific TAVR procedures performed at UCMC during the relevant time period that were billed to the Government; made allegations and submitted an email chain involving UCP and UCMC officials concerning Dr. Shreenivas' failure to complete the OP note to bill the Government; and submitted his employment agreement indicating that UCP was an entity which was assigned billing responsibilities for UCP physicians. These allegations, when coupled with the allegations that UCP presented or caused to be presented claims for reimbursement relating to TAVR procedures that did not meet the NCD criteria for payment, create a strong inference that UCP presented or caused to be presented false claims for payment to the Government and satisfy Relator's burden to plead his fraud claims against UCP with particularity.

First, Relator has obtained a TAVR case log from Rhonda Schlesinger, "a billing code manager for UCMC, UCP, UC Health, and UC Physicians." (Doc. 20, ¶ 73). Relator alleges that from December 14, 2015 through August 22, 2017, physicians employed by UCP, Drs. Shreenivas and Arif, performed 33 TAVR procedures at UCMC, at least 12 of which were billed to Medicare, CareSource (Ohio Medicaid), and the Veterans Administration-TriCare/Champus. (*Id.*, ¶ 77). The log identifies the payment status for Drs. Shreenivas and Arif's TAVR patients by patient initials, medical record number, CPT Code (specifying a TAVR procedure), the date the TAVR procedure was performed, the "date posted," the specific invoice number, and the identity of the governmental insurance carrier (Medicare, VA, or CareSource). (*Id.*, ¶ 77). Relator alleges that since August of 2017, Dr. Arif of UCP has performed 21 additional TAVR procedures at UCMC which UC Physicians has billed or caused to be billed to the United States. (*Id.*, ¶ 78). This information provides strong support that the Government was billed for TAVR procedures at a time when, according to the facts alleged in the complaint, neither the facility nor the physicians had the requisite volume of AVR procedures to bill the Government for such procedures.

UCP argues that no relaxed pleading standard should apply in this case because unlike the relator in *Prather I*, Relator here has no first-hand knowledge about UCP's billing practices. The Court disagrees. The defendant in *United States v. Millennium Radiology, Inc.*, No. 1:11-cv-825, 2014 WL 4908275 (S.D. Ohio Sept. 30, 2014), similarly argued that the Rule 9(b) requirements should not be relaxed because the relator had no personal knowledge of the defendant's claims process. In that case, the relator pointed to nine monthly "aging reports" that identified charges made by the defendant to the Medicare and Medicaid programs. The Court stated:

> While establishing "personal knowledge" is one way to create an inference that a claim was submitted, it is not the only means. "'[W]here a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme,' those examples may suffice where they are 'representative samples of the broader class of claims.'" *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 503 (6th Cir. 2008) (quoting *United States ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 510 (6th Cir. 2007). Here, the aging reports show that MRI submitted claims for payment to the government, the amounts submitted and the times submitted. The Court finds in this instance, these examples are sufficient to allege the presentation of a false claim for payment to the government. *See United States ex rel. Repko v. Guthrie Clinic,* 557 F. Supp. 2d 522, 527 (M.D. Pa. 2008) ("attachment of some or all of the allegedly fraudulent claims would serve no further purpose consistent with Rule 9(b) because defendants are on notice that the basis of the alleged fraud in each claim is the relationship between the defendants, not anything unique to a particular claim, that has caused these claims to be allegedly fraudulent").

Millennium Radiology, 2014 WL 4908275, at *9. Like the aging reports in *Millennium Radiology*, the TAVR case logs in this case provide the requisite who, what, when, and how specifics under Rule 9.[18]

Second, the email chain concerning Dr. Shreenivas' failure to complete the OP note for billing purposes adds further support for the conclusion that actual false claims in all likelihood were submitted to the Government for payment. Dr. Naber sought the assistance of Peter Clayton, the Executive Director for Business Affairs for UC Health and UCP, in obtaining Dr. Shreenivas' OP note. (Doc. 20, ¶ 70). Dr. Shreenivas advised both Mr. Clayton and Dr. Naber that the procedure could not be billed, and on February 3, 2016, Dr. Naber stated, "*We will be billing only Medicare* (not the patient) so we still need the dictation to do this properly." (*Id.*, ¶

[18] UCP contends that "even if the claims included in his Amended Complaint were based on a TAVR case log, Relator's Amended complaint still does not *establish* that those claims were submitted by UCP." (Doc. 38 at 12) (emphasis added). At the pleading stage, Relator need not "establish" or prove that UCP submitted the claims but need only plead that UCP submitted or caused to be submitted claims to the government for payment. Relator has done so in this case.

72) (emphasis added). The log showed that one and a half months later, the Government was invoiced for Dr. Shreenivas' TAVR patient (RT MR04020680). (*Id.*, ¶ 77).

Third, while Relator has not alleged that he was involved in billing for TAVRs at UCMC or familiar with billing procedures, unlike the relator in *Prather I*, he has alleged facts explaining the circumstances why he "cannot produce such allegations." *Bledsoe II*, 501 F.3d at 504 n.12. The Amended Complaint alleges that UCP and UC Physicians knowingly submitted or caused to be submitted Part B professional fees to the government for TAVR procedures. (Doc. 20, ¶ 86). Pursuant to the "University of Cincinnati Physicians, Inc. Physician Employment Agreement" between Relator and UCP, which was in effect during the relevant time period in this case, physicians are not responsible for billing. Rather, under the employment agreement, physicians employed by UCP specifically assigned "to UCP and UCPC [UC Physicians] all billings for all Services render by Physician." (*Id.*, Ex. 1, ¶ 9). The Agreement provides that "UCP or UCPC shall exclusively bill . . . in a manner determined at their sole discretion in accordance with applicable Federal . . . law. . . ." (*Id.*). The Agreement thus indicates that *both* UCP and UC Physicians were assigned billing responsibilities. When considered in light of the allegations in the amended complaint that UCP presented or caused to be presented claims for TAVR procedures that failed to comply with the TAVR NCD (Doc. 20, ¶¶ 2, 52, 54, 55), the Agreement provides additional inferential support for the conclusion that Relator's allegations against UCP are sufficient.

UCP contends that the Agreement concerning the manner of billing is in the disjunctive, and Relator has failed to allege any specific claims that UCP actually billed. At this juncture, however, the Court finds that Relator has sufficiently alleged facts to put UCP on notice of the basis of Relator's FCA claim. The alleged facts also give UCP sufficient notice of the

relationship between the alleged fraud, which is the same for each TAVR claim submitted by UCP and the other defendants, and the identity of the entities responsible for billing the Government for physician services. Each instance of alleged fraud - billing the Government for TAVR procedures when the NCD volume requirements were not met - is detailed in the log of TAVR procedures. Relator has provided the necessary factual predicates to convince the Court that in all likelihood, UCP submitted actual false claims by billing for the procedures detailed in the log. These factual predicates are the Agreement which assigns billing responsibilities to both UCP and UC Physicians; Dr. Naber's representations that "only Medicare" will be billed"; and the allegations of the Amended Complaint that UCP submitted or caused to be submitted to the Government claims for reimbursement for TAVR procedures that do not qualify for reimbursement. Viewing these allegations in context and reading them together in the light most favorable to Relator, as the Court must do on a motion to dismiss, the Court concludes that Relator has pled "sufficient detail—in terms of time, place and content, the nature of a defendant's fraudulent scheme, and the injury resulting from the fraud—to allow [UCP] to prepare a responsive pleading. . . ." *SNAPP I,* 532 F.3d at 504. At this juncture, Relator has sufficiently alleged in detail the basis for his fraud claim against UCP and that UCP presented or caused to be presented claims to the Government for reimbursement relating to TAVR procedures that do not qualify for reimbursement.[19]

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[19] The Court acknowledges that Relator has named multiple defendants and made some seemingly inconsistent allegations in his amended complaint about which entity submitted claims for payment and who played what role in the alleged fraudulent scheme. This is based, in part, on the UC Health defendants' assertion in a Court filing "based on information and belief" that UC Physicians submitted the claims. (Doc. 18 at 8 n.6). The amended complaint alleges that UCP employs physicians and leases those physicians to UC Physicians, and UC Health is the sole member of UC Physicians. (Doc. 20, ¶ 13). Whether UC Physicians, as the UC Health defendants suggest, or UCP (which leases its physicians to UC Physicians) submitted or "caused to be submitted" the particular claims identified in the amended complaint to the Government for payment of professional fees may depend on the corporate relationship between the entities and other factors, which will undoubtedly be fleshed out during discovery. The Court declines to dismiss UCP from this case based on allegations filed "on information and belief" by the UC Health defendants.

2. Scienter

UCP contends that Relator has failed to allege sufficient facts to satisfy the scienter requirement of his FCA claim as to UCP. UCP argues that "where, as here, there are no sufficient factual allegations as to UCP, there are no factual allegations as required to find that Relator has properly alleged scienter and dismissal on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) is appropriate." (Doc. 25 at 10).

The Sixth Circuit explained the scienter requirement in *Prather II* as follows:

> "False Claims Act liability for failing to disclose violations of legal requirements" will not attach unless "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996. The Act "defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Id.* (quoting 31 U.S.C. § 3729(b)(1)(A)). "Knowing" and "knowingly" does not require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). And, at the motion-to-dismiss stage, a plaintiff need only allege the scienter element generally. Fed. R. Civ. P. 9(b).
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> "[A]n aggravated form of gross negligence (i.e. reckless disregard) will satisfy the scienter requirement for an FCA violation." *United States ex rel. Wall v. Circle C Constr., L.L.C.*, 697 F.3d 345, 356 (6th Cir. 2012) (alteration in original) (quoting *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008)). Congress added the "reckless disregard" prong to the definition of knowledge in the False Claims Act "to target that defendant who has 'buried his head in the sand' and failed to make some inquiry into the claim's validity." *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (quoting S. Rep. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286). This inquiry must be "reasonable and prudent under the circumstances." *Id.* (quoting S. Rep. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. at 5286).

892 F.3d at 837.

Relator has alleged sufficient facts that support the reasonable inference that UCP acted with "reckless disregard" in submitting TAVR claims without having satisfied the volume requirements of the TAVR NCD. In 2015, Dr. Shreenivas informed Dr. Richard Becker, who was the Chief of the Division of Cardiology, Health & Disease for UCMC, that UCMC had not

performed the required number of AVRs to meet the TAVR NCD and requested review by UCMC's legal department. (Doc. 20, ¶ 66). Jamie Hamm, the billing coordinator for UC Health, UCMC, and UCP, advised Dr. William Naber, the Medical Director at UCMC, that Dr. Shreenivas had not provided the necessary OP dictation to bill patient account number MR04020680. (Doc. 20, ¶ 69, Ex. 8). In turn, Dr. Naber sought assistance from Peter Clayton, the Executive Director for Business Affairs for UC Health and UCP, who then advised Dr. Shreenivas to complete his dictation or "advise of difficulties." (*Id.*, ¶ 70, Ex. 8). Dr. Shreenivas informed Dr. Naber and Mr. Clayton that RT MR04020680 could not be billed. (*Id.*, ¶ 71, Ex. 8). Dr. Naber responded on February 3, 2016:

> I have talked to Craig Cain about this case, he was peripherally aware. We will be billing only Medicare (not the patient) so we still need the dictation to do this properly. Thanks for all of your help clarifying this delicate situation.

(*Id.*, ¶ 72). Additionally, Dr. Tim Smith, a former employee of UCP, told Dr. Gregory Rouan, the Chairman of the Department of Internal Medicine for UCMC, and Dr. Charles Hattemer, the Associate Chief of Clinical Affairs at UCMC and a member of UCP, that billing government sponsored health care programs for TAVR procedures when the NCD prerequisites had not been met for AVR volume was unlawful. (*Id.*, ¶ 75). These factual allegations support the inference that UCP was on notice that the submission of TAVR claims to the Government for payment in the absence of meeting the NCD volume prerequisites was unlawful, but such claims were nevertheless presented for payment. (Id., ¶¶ 74, 77-78). Therefore, the Court concludes that Relator has adequately alleged scienter under the FCA.[20]

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[20] UCP also alleges that "Relator's new 'conspiracy' to commit fraud claim is likewise deficient in alleging any specific facts in support, alleging only that the UC Defendants and UCP 'shared in the general conspiratorial objective' to submit false claims." (Doc. 25 at 12). UCP has waived this argument by alluding to it in a cursory manner and failing to develop the argument factually or legally. *Kuhn v. Washtenaw County*, 709 F.3d 612, 624 (6th Cir. 2013) (stating that the Sixth Circuit "has consistently held that arguments not raised in a party's opening brief, as well as arguments adverted to in only a perfunctory manner, are waived.") (citing *Caudill v. Hollan*, 431 F.3d 900, 915 n.13 (6th Cir. 2005) (citing decisions that stand for these two related propositions)). *See also*

IT IS THEREFORE ORDERED THAT:

1) The UC Health defendants' motion to strike the amended complaint as untimely (Doc. 23) is **DENIED.**

2) Relator's motion for leave to file a first amended complaint (Doc. 27) is **GRANTED**. The Clerk is directed to file the proposed amended complaint (Doc. 27-1).

3) The United States' motion to file a reply in support of Statement of Interest (Doc. 40) is **GRANTED**. The Reply (Doc. 40, Exh. A) is deemed filed.

IT IS THEREFORE RECOMMENDED THAT:

1) The UC Health defendants' motion to dismiss the complaint (Doc. 10) be **DENIED.**

2) UCP's motion to dismiss the complaint (Doc. 17) be **DENIED** as moot.

3) UCP's motion to dismiss the amended complaint (Doc. 25) be **DENIED**.

Date: 3/20/2020

s/Karen L. Litkovitz
Karen L. Litkovitz
United States Magistrate Judge

McPherson v. Kelsey, 125 F.3d 989, 995-96 (6th Cir. 1997) ("It is not sufficient for a party to mention a possible argument in the most skeletal way, leaving the court to . . . put flesh on its bones.").

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES *ex rel.*,
DONALD LYNCH, M.D.,
Plaintiff-Relator,

vs.

UNIVERSITY OF CINCINNATI
MEDICAL CENTER, LLC, *et al.*,
Defendants.

Case No. 1:18-cv-587
Dlott, J.
Litkovitz, M.J.

NOTICE

Pursuant to Fed. R. Civ. P. 72(b), **WITHIN 14 DAYS** after being served with a copy of the recommended disposition, a party may serve and file specific written objections to the proposed findings and recommendations. This period may be extended further by the Court on timely motion for an extension. Such objections shall specify the portions of the Report objected to and shall be accompanied by a memorandum of law in support of the objections. If the Report and Recommendation is based in whole or in part upon matters occurring on the record at an oral hearing, the objecting party shall promptly arrange for the transcription of the record, or such portions of it as all parties may agree upon, or the Magistrate Judge deems sufficient, unless the assigned District Judge otherwise directs. A party may respond to another party's objections **WITHIN 14 DAYS** after being served with a copy thereof. Failure to make objections in accordance with this procedure may forfeit rights on appeal. *See Thomas v. Arn*, 474 U.S. 140 (1985); *United States v. Walters*, 638 F.2d 947 (6th Cir. 1981).